

# EXHIBIT B

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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

NOVAPLAST CORPORATION,  
Plaintiff,

v.

INPLANT, LLC and PROXIMATE  
CONCEPTS, LLC,  
Defendants.

Civil Action No.  
2:20-cv-7396-KM-JBC

**DEFENDANTS' AMENDED INVALIDITY CONTENTIONS**

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## I. INTRODUCTION

Pursuant to the Court’s Pre-Trial Scheduling order Dkt. 47 and L. Pat. R. 3.3,~~and 3.4,~~ and 3.7, Defendants INPLANT, LLC and PROXIMATE CONCEPTS, LLC, (collectively “Defendants,” individually “Defendant”) hereby serve Defendants’ Amended Invalidity Contentions concerning U.S. Patent No. 10,105,213 (the “’213 Patent” or “Patent-in-Suit”)~~and the accompanying document production.~~

These Amended Invalidity Contentions, which comprise this statement and the accompanying claim charts, set forth Defendants’ Amended Invalidity Contentions with respect to the following Asserted Claims identified by Plaintiff NovaPlast Corporation (“NovaPlast” or “Plaintiff”) in its Infringement Contentions: claims 1 and 5 of the ‘213 Patent (collectively, the “Asserted Claims”)in light of the Court’s [Markman] Opinion & Order dated July 26, 2023 (Dkt. 73) (the “Markman Order”). These Amended Invalidity Contentions, including the charts attached hereto as Exhibits 1–~~744~~, identify certain prior art currently known to Defendants that anticipates and/or renders obvious the patent claims at issue under 35 U.S.C. §§ 102 and/or 103. These Amended Invalidity Contentions including the charts attached hereto point out, as non-limiting examples, where in the prior art the claim elements are found. These Amended Invalidity Contentions further disclose other grounds of invalidity based on 35 U.S.C. §§ 101 and 112.

~~Defendants provide these Invalidity Contentions based on the claim scope and constructions that NovaPlast appears to advance in its Infringement Contentions served on the Defendants on February 28, 2022. Defendants’ contentions herein should not be seen as a suggestion that NovaPlast’s reading of the patent claims is correct. These Invalidity Contentions are not, and should in no way be seen as, adoptions or admissions as to the accuracy of that scope or construction, or an assertion of a particular construction by Defendants or position as to whether preambles in the Asserted Claims are limiting.~~

These Amended Invalidity Contentions are based on Defendants' current knowledge of the Patent-in-Suit, the prior art, and the Infringement Contentions. As such, Defendants are continuing to investigate the prior art, and Defendants reserve the right to supplement or otherwise amend these Amended Invalidity Contentions, including the charts attached hereto, as may be appropriate. Defendants also reserve the right to amend further these Amended Invalidity Contentions ~~in view of the claim constructions adopted by the Court;~~ upon any Court determination of the priority dates of the Asserted Claims that is earlier than the filing dates of the Patent-in-Suit; in view of discovery concerning the alleged priority, conception, and reduction to practice dates for any of the Asserted Claims; in view of additional prior art obtained through discovery or further investigation, including from third parties by subpoena or otherwise; and/or to the extent that NovaPlast seeks to amend its Infringement Contentions or otherwise elaborate on its infringement theories.

Defendants have identified exemplary portions of the references based on presently available information to avoid excessive, cumulative citations. Citations to particular excerpts are exemplary in nature, and are not exhaustive of the evidentiary support found in the references. Defendants reserve the right to rely on additional support contained in the references that may further disclose, either expressly or inherently, and/or render obvious one or more elements of the Asserted Claims, or otherwise provide context or aid in understanding the references. Defendants reserve the right to rely on any evidence, including expert testimony, and statements and admissions by NovaPlast in the above-captioned litigation to prove inherency, enablement, and/or the meaning of the prior art.

Defendants may further rely on prior art cited herein, as well as other relevant materials and information, including fact and expert testimony about the prior art, to show the state of the art in the relevant timeframes. Defendants may also rely on the "Background of the Invention" and

other relevant portions of the Patent-in-Suit and any related patents, including their prosecution and reexamination file histories.

## **II. PRIOR ART UNDER 35 U.S.C. § 102**

Defendants identify the following items of prior art that anticipate and/or render obvious the Asserted Claims, either expressly or inherently as understood by a person having ordinary skill in the art at the time of the alleged invention, either alone or in combination with the knowledge of one of ordinary skill in the art and/or in combination with other references identified herein. Defendants may further rely on testimony from the authors and custodians of these references and systems, including other witnesses with relevant knowledge regarding the design and operation of the prior art systems identified herein. These references and the systems they describe are prior art under at least 35 U.S.C. §§ 102(a) as enumerated below, and described in the attached claim charts.

*See Exhibits 1–11.<sup>±</sup>*

1. U.S. Pat. No. 5,121,779 to Green ("Green"), ~~Exhibit 1~~, which is prior art under at least §102(a).
2. U.S. Pat. No. 9,168,126 to Preissman ("Preissman '126"), Exhibit ~~21~~, which is prior art under at least §102(a).
3. U.S. App. Pub. No. 2014/0228951 to Zochowski ("Zochowski"), Exhibit ~~23~~, which is prior art under at least §102(a).
4. U.S. App. Pub. No. 2015/0032208 to Priessman ("Priessman '208"), Exhibit ~~34~~, which is prior art under at least §102(a).
5. U.S. Pat. No. 5,078,189 to Ronsonet ("Ronsonet"), Exhibit ~~45~~, which is prior art under at least §102(a).

6. U.S. Pat. No. 4,651,504 to Bentsen (“Bentsen”), ~~Exhibit 6~~, which is prior art under at least §102(a).
7. U.S. Pat. No. 4,825,915 to Hess (“Hess”), ~~Exhibit 7~~, which is prior art under at least §102(a).
8. U.S. Pat. No. 8,690,428 to Kruse (“Kruse”), Exhibit 58, which is prior art under at least §102(a).
9. U.S. Pat. No. 8,262,289 to Fratti (“Fratti”), Exhibit 69, which is prior art under at least §102(a).
10. U.S. Pat. App. Pub. No. 2007/0038310 to Guetty (“Guetty”), Exhibit 740, which is prior art under at least §102(a).
11. U.S. Pat. No. 8,211,173 to Keller (“Keller”), ~~Exhibit 11~~, which is prior art under at least §102(a).

Defendants have omitted Green, Bentsen, Hess and Keller from Defendants’ specific contentions as to invalidity of the Asserted Claims for anticipation or obviousness under 35 U.S.C. §§ 102 and 103. Nevertheless, Green, Bentsen, Hess and Keller are identified herein for at least being background art disclosing known techniques relating to the technology of the Asserted Claims as respectively shown in Exhibits 1, 6-7 and 11 of Defendants’ Initial Invalidity Contentions. To the extent Plaintiff contends that Defendants’ Accused Products 1 and 2 read on the Asserted Claims for practicing prior-art technology disclosed in Green, Bentsen, Hess and Keller, Defendants reserve the right to rely on the teachings of at least Green (*see, e.g.*, Green, Abstract, 1:4, 1:54-65, 2:6-21, 2:51-3:2, 3:6-22, FIG. 5), Bentsen (*see, e.g.*, Bentsen, 1:5-13, 2:33-58, 2:66-3:30, 8:31-52, FIGS. 1-3 and 5), Hess (*see, e.g.*, Hess Abstract, 3:49-57, 4:51-62, 7:23-40, 8:22-36 and FIGS. 3-5) and Keller (*see, e.g.*, Keller, Abstract, 2:61-65, FIG. 2, 4:6-8) to support Defendants’ claims of invalidity for obviousness or non-infringement.

Defendants might also rely on the prior art of record for any permissible purpose, including prior art discussed in the Asserted Patent specification itself or the prosecution file histories of the Asserted Patent and any related patents or patent applications, including to show that one or more of the Asserted Claims are anticipated by or would have been obvious, to show the state of the art, show a person of ordinary skill in the art's motivation to combine a reference with one or more other references, and to show the proper scope of the claims.

### **III. INVALIDITY BASED ON ANTICIPATION UNDER 35 U.S.C. § 102**

Defendants identify the following items of prior art that anticipate the Asserted Claims, either expressly or inherently as understood by a person having ordinary skill in the art at the time of the alleged invention.

1. Preissman '126 anticipates Asserted Claim 1.
- ~~1-2.~~ Priessman '208 anticipates Asserted Claim 1.
- ~~2-3.~~ Zochowski anticipates Asserted Claims 1 and 5.
- ~~3-4.~~ Kruse anticipates Asserted Claims 1 ~~and 5.~~
- ~~4-5.~~ Fratti anticipates Asserted Claims 1 and 5.
- ~~5-6.~~ Guetty anticipates Asserted Claims 1 and 5.

### **III. INVALIDITY BASED ON OBVIOUSNESS UNDER 35 U.S.C. § 103**

The Asserted Claims simply combine elements well known in the art and yield no more than one skilled in the art would expect from such a combination. The prior art cited in these invalidity contentions are analogous art to the Patent-in-Suit in that the prior art citations are from the same field of endeavor as the Patent-in-Suit or are reasonably pertinent to the particular problem that the purported invention of the Asserted Claims. *See e.g., Wyers v. Master Lock Co.*, 616 F.3d 1231, 1237 (Fed. Cir. 2010) (“Two criteria are relevant in determining whether prior art is analogous: ‘(1) whether the art is from the same field of endeavor, regardless of the problem



addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.”—citations omitted). When confronted with the alleged problems described in the Patent-in-Suit—providing a device for delivery of an object, such as a prosthetic implant, having an appropriately sized distal opening—one of ordinary skill in the art at the time of the alleged inventions would have been motivated to consider the techniques taught by the prior art cited in these Amended Invalidity Contentions, including the prior art medical devices in the same field of endeavor (e.g., the “Keller Funnel” prosthetic implant delivery devices of, say, Priessman ‘126 and Priessman ‘208, ~~Keller~~, and other implant delivery bags or funnels of, say, Zochowski and Guetty) as well as the prior art directed to funnels and recloseable bags that are flexible, elongated and specifically directed to containing and/or dispensing contents through an appropriately sized opening (e.g., ~~Green~~, Ronsonet, ~~Bentsen~~, ~~Hess~~, Kruse, and Fratti), and to combine such teachings to arrive at the alleged invention claimed in the Patent-in-Suit. This is demonstrated by the cited prior art, which disclose all of the elements of the Asserted Claims, as well as motivations to modify or combine their individual teachings. The cited prior art share commonalities in terms of their general applicability to devices, such as recloseable bags, funnels and bag-like or funnel-like medical devices, for containing and/or dispensing materials or objects, which can include a prosthetic implant. To the extent it is argued that any cited prior art does not expressly disclose a particular claim or element, it would have been inherent in the disclosure and/or obvious to a person of ordinary skill in the art to include the claimed element to perform the invention as claimed in the Patent-in-Suit.

The U.S. Supreme Court decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S.Ct. 1727, 1739 (2007)(“*KSR*”), held that patents based on allegedly new combinations of elements or components already known in a technical field may be found to be obvious.

Specifically, the Court in *KSR* rejected a rigid application of the previously employed “teaching, suggestion, or motivation [to combine]” test. *Id.* at 1741. “In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim.” *Id.* at 1741-42. “Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *Id.* at 1742. In particular, the Supreme Court emphasized the principle that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at 1739. A key inquiry is whether the “improvement is more than the predictable use of prior art elements according to their established function.” *Id.* at 1740.

In view of *KSR*, the PTO issued a set of Examination Guidelines. Examination Guidelines for Determining Obviousness Under 35 U.S.C.103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57,526 (Oct. 10, 2007). Those Guidelines identified various rationales for finding a claim obvious, including:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of a known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) “Obvious to try”—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art;

(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

*Id.* at 57,529.

As described in the attached charts, all the elements of the Asserted Claims were commonplace before the Patent-in-Suit's December 29, 2015, earliest possible priority date. For each element, there exists evidence from the cited prior art that it was well known in the art prior to December 29, 2015. To the extent it is argued any of the cited prior art references do not anticipate the Patent-in-Suit, it would have been obvious to a person of ordinary skill in the art that the Patent-in-Suit are merely a combination of well-known methods and systems resulting in expected results, including choosing features from among a finite number of identified, predictable solutions, with a reasonable expectation of success.

**A. Invalidity of the '213 Patent based on obviousness under 35 U.S.C. § 103**

With respect to the '213 Patent, for example, the cited prior art references disclose a delivery system adapted to facilitate insertion of a prosthetic implant through a surgical opening. As illustrated in the attached charts, these cited prior art references include, for example and without limitation:

~~Green~~, Preissman '126, Zochowski, Priessman '208, Ronsonet, ~~Bentsen, Hess, Kruse, Fratti, and~~  
Guetty, and Keller.

In fact, the '213 Patent itself describes flexible tapered funnel or bag-like devices to aid in inserting a breast implant through an incision, as known in the art. *See* '213 Patent at 1:41–56. Priesman

'126, Zochowski, Priessman '208 and Guetty similarly disclose such an implant delivery device. The prior art directed to funnels and recloseable bags, namely Ronsonet, Kruse and Fratti, each disclose flexible, elongated delivery systems for containing and/or dispensing contents, which can include implants, through an appropriately sized opening that have the structure recited in the Asserted Claims and are capable of inserting a prosthetic implant. A person of ordinary skill in the art would thus have been motivated to combine these references with any of the references included in Defendants' Invalidity Contentions because it was well known to provide a delivery system adapted to facilitate insertion of a prosthetic implant through a surgical opening. Any of these combinations would thus have rendered at least these elements obvious.

As another example, the cited prior art references disclose a delivery system comprising a flexible elongated member defining a proximal end and a distal end, the proximal end formed opposite the distal end and defining a closed end, the distal end defining a longitudinal opening. As illustrated in the attached charts, these cited prior art references include, for example and without limitation:

Preissman '126, Zochowski, Priessman '208, ~~Bentsen~~, Kruse, Fratti, and Guetty, ~~and Keller~~. In fact, the '213 Patent itself describes flexible tapered funnel or bag-like devices to aid in inserting a breast implant through an incision in which the device has an open distal end and a proximal end that is closed and squeezed by a surgeon to urge the breast implant therethrough, as known in the art. *See* '213 Patent at 1:41–56. Priesman '126, Zochowski, Priessman '208 and Guetty similarly disclose such an implant delivery device. Kruse and Fratti also disclose analogous flexible elongated bag-like devices have open distal ends and closed proximal ends. A person of ordinary skill in the art would thus have been motivated to combine these references with any of the references included in Defendants' Invalidity Contentions because it was well known to provide a delivery system comprising a flexible elongated member defining a proximal end and a distal end,

the proximal end formed opposite the distal end and defining a closed end, the distal end defining a longitudinal opening. Any of these combinations would thus have rendered at least these elements obvious.

As another example, the cited prior art references disclose the distal end including a first longitudinal edge and a second longitudinal edge, the first longitudinal edge and second longitudinal edge further defining the longitudinal opening. As illustrated in the attached charts, these cited prior art references include, for example and without limitation:

~~Green~~, Priessman '126, Zochowski, Priessman '208, Ronsonet, ~~Bentsen~~, ~~Hess~~, Kruse, Fratti, and Guetty.

In fact, the '213 Patent itself describes flexible tapered funnel or bag-like devices to aid in inserting a breast implant through an incision in which the device has a second opening for inserting materials and/or objects into the device, as known in the art. *See* '213 Patent at 1:41–56. Furthermore, each of Priessman '126, Zochowski, Priessman '208, Ronsonet, Kruse, Fratti, and Guetty each disclose a longitudinal opening extending from a distal end opening, and which is closed using fasteners. A person of ordinary skill in the art would thus have been motivated to combine these references with any of the references included in Defendants' Invalidity Contentions because it was well known to provide a delivery system comprising a distal end including a first longitudinal edge and a second longitudinal edge, the first longitudinal edge and second longitudinal edge further defining the longitudinal opening. Any of these combinations would thus have rendered at least these elements obvious.

As another example, the cited prior art references disclose at least one first fastener formed on the elongated member adjacent the first longitudinal edge, and a second fastener formed on the elongated member adjacent the second longitudinal edge. As illustrated in the attached charts, these cited prior art references include, for example and without limitation:

~~Green~~, Preissman '126, Zochowski, Priessman '208, Ronsonet, ~~Bentsen~~, Kruse, Fratti, and Guetty.

A person of ordinary skill in the art would thus have been motivated to combine these references with any of the references included in Defendants' Invalidity Contentions because it was well known to provide a delivery system comprising at least one first fastener formed on the elongated member adjacent the first longitudinal edge, and a second fastener formed on the elongated member adjacent the second longitudinal edge. Any of these combinations would thus have rendered at least these elements obvious.

As another example, the cited prior art references disclose the second fastener adapted to matingly engage with the at least first fastener and to close the longitudinal opening. As illustrated in the attached charts, these cited prior art references include, for example and without limitation:

~~Green~~, Preissman '126, Zochowski, Priessman '208, Ronsonet, ~~Bentsen~~, Kruse, Fratti, and Guetty.

A person of ordinary skill in the art would have been motivated to combine these references with any of the references included in Defendants' Invalidity Contentions because it was well known to provide a delivery system comprising the second fastener adapted to matingly engage with the at least first fastener and to close the longitudinal opening. Any of these combinations would thus have rendered at least these elements obvious.

As another example, the cited prior art references disclose a delivery device whereby a predetermined size distal opening is formed based on the engagement of the second fastener with the at least one first fastener, the distal opening sized to allow the prosthetic implant to be urged therethrough. As illustrated in the attached charts, these cited prior art references include, for example and without limitation:

~~Green, Preissman '126, Preissman '208, Zochowski, Ronsonet, Bentsen, Hess, Kruse, Fratti, and~~  
 Guetty.

In fact, the '213 Patent itself describes implant insertion devices having distal openings sized to allow a prosthetic implant to be urged therethrough as known in the art. *See* '213 Patent at 1:41–56. The prior art directed to implant delivery devices, namely, Zochowski, Priesman '126, Priesman '208 and Guetty each disclose devices having a distal opening formed by closure of two opposing edges of a longitudinal opening using fasteners and that opening being of a predetermined size, and which size can allow a prosthetic implant to be urged therethrough. Additionally, the prior art directed to funnels also collectively teaches only a limited number of ways to form an opening or define the size of the opening: first, providing perforations at the distal end as in Hess, second, using a scissors to cut the distal opening to size as shown in at least Bentson, and third with fasteners having multiple selectable positions as shown in at least Ronsonet, each of which is predictable with a reasonable expectation of success, and thus obvious to try under *KSR*. A person of ordinary skill in the art would thus have been motivated to combine these references with any of the references included in Defendants' Invalidity Contentions because it was well known to provide a delivery system whereby a predetermined size distal opening is formed based on the engagement of the second fastener with the at least one first fastener, the distal opening sized to allow the prosthetic implant to be urged therethrough. Any of these combinations would thus have rendered at least these elements obvious. Additionally, it is apparent from the prior art that Accused Products 1 and 2, which are configured to have a distal opening sized by a) cutting off the tip (Accused Product 1) and b) by providing a perforated tip and/or cutting off the tip (Accused Product 2) are merely practicing the known prior art.

As another example, the cited prior art references disclose a delivery device having ~~at least one~~ a plurality of first fasteners ~~further~~ comprising a channel, the second fastener defining a

shoulder, the shoulder adapted to be received within and secured with the channel of at least one of the first fasteners, as further recited in asserted claim 5. As illustrated in the attached charts, these cited prior art references include, for example and without limitation:

Zochowski, ~~Priessman '208~~, Ronsonet, ~~Bentsen~~, ~~Kruse~~, Fratti, and Guetty.

A person of ordinary skill in the art would have been motivated to combine these references with any of the references included in Defendants' Invalidity Contentions because it was well known to provide a delivery system whereby a predetermined size distal opening is formed based on the engagement of the second fastener with the at least one first fastener, the distal opening sized to allow the prosthetic implant to be urged therethrough. Any of these combinations would thus have rendered at least these elements obvious.

**B. Summary - Invalidity of the Asserted Claims based on obviousness under 35**

**U.S.C. § 103**

Accordingly, Defendants identify the following exemplary prior art references that either alone or in combination with other prior art or knowledge of one of ordinary skill (including any of the above anticipatory prior art) renders the Asserted Claims invalid as obvious under 35 U.S.C. § 103 as detailed in the attached claim charts:

1. ~~Green and one or more of (A) any of Preissman '126, Zochowski, Priessman '208, Ronsonet, Bentsen, Hess, Kruse, Fratti, Guetty, and Keller, alone or in combination, and/or (B) knowledge of a person of ordinary skill.~~
2. Preissman '126 and one or more of (A) any of ~~Green~~, Zochowski, ~~Priessman '208~~, Ronsonet, ~~Bentsen~~, ~~Hess~~, ~~Kruse~~, ~~Fratti~~, and Guetty, ~~and Keller~~, alone or in combination, and/or (B) knowledge of a person of ordinary skill.



3. Zochowski and one or more of (A) any of ~~Green~~, Preissman '126, Priessman '208, Ronsonet, ~~Bentsen~~, ~~Hess~~, Kruse, Fratti, and Guetty, ~~and Keller~~, alone or in combination, and/or (B) knowledge of a person of ordinary skill.
4. Priessman '208 and one or more of (A) any of ~~Green~~, ~~Preissman '126~~, Zochowski, Ronsonet, ~~Bentsen~~, ~~Hess~~, ~~Kruse~~, Fratti, and Guetty, ~~and Keller~~, alone or in combination, and/or (B) knowledge of a person of ordinary skill.
5. Ronsonet and one or more of (A) any of ~~Green~~, ~~Preissman '126~~, Zochowski, Priessman '208, ~~Bentsen~~, ~~Hess~~, Kruse, Fratti, and Guetty, ~~and Keller~~, alone or in combination, and/or (B) knowledge of a person of ordinary skill.
6. ~~Bentsen and one or more of (A) any of Green, Preissman '126, Zochowski, Priessman '208, Ronsonet, Hess, Kruse, Fratti, Guetty, and Keller, alone or in combination, and/or (B) knowledge of a person of ordinary skill.~~
7. ~~Hess and one or more of (A) any of Green, Preissman '126, Zochowski, Priessman '208, Ronsonet, Bentsen, Kruse, Fratti, Guetty, and Keller, alone or in combination, and/or (B) knowledge of a person of ordinary skill.~~
- 8.6. ~~Kruse and one or more of (A) any of Green, Preissman '126, Zochowski, Priessman '208, Ronsonet, Bentsen, Hess, and Fratti, and Guetty and Keller, alone or in combination, and/or (B) knowledge of a person of ordinary skill.~~
- 9.7. ~~Fratti and one or more of (A) any of Green, Preissman '126, Zochowski, Priessman '208, Ronsonet, Bentsen, Hess, Kruse, and Guetty, and Keller, alone or in combination, and/or (B) knowledge of a person of ordinary skill.~~
- 10.8. ~~Guetty and one or more of (A) any of Green, Preissman '126, Zochowski, Priessman '208, Ronsonet, Bentsen, Hess, Kruse, and Fratti, and Keller, alone or in combination, and/or (B) knowledge of a person of ordinary skill.~~

11. ~~\_\_\_\_ Keller and one or more of (A) any of Green, Preissman '126, Zochowski, Priessman '208, Ronsonet, Bentsen, Hess, Kruse, Fratti and Guetty, alone or in combination, and/or (B) knowledge of a person of ordinary skill.~~

#### IV. **INVALIDITY BASED ON 35 U.S.C. § 101**

The Asserted Claims are invalid for lack of utility. The utility requirement of 35 U.S.C § 101 mandates that any patentable invention be useful and, accordingly, the subject matter of the claim must be operable. ... [W]hen an impossible limitation, such as a nonsensical method of operation, is clearly embodied within the claim, the claimed invention must be held invalid. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358–59 (Fed. Cir. 1999).

Claim 1 requires a “the distal end defining a longitudinal opening.” In direct conflict to the foregoing recitations, claim 1 further requires “the first longitudinal edge and second longitudinal edge further defining the longitudinal opening.” It is impossible to build a functional device that has a longitudinal opening defined by opposing longitudinal edges where the distal end also defines a longitudinal opening. Moreover, in direct conflict to claim 1 requiring “a longitudinal opening,” claim 1 further requires that the longitudinal opening be closed. It is impossible to build a device in which a longitudinal opening is both open and closed. Accordingly, for at least this reason, the Asserted Claims are inoperable and invalid for lack of utility under 35 U.S.C § 101.

#### V. **INVALIDITY BASED ON 35 U.S.C. § 112**

The following contentions are subject to revision and amendment pursuant to Federal Rule of Civil Procedure 26(e) and the Orders of record in this matter to the extent appropriate in light of further investigation and discovery regarding the defenses, ~~NovaPlast’s proposed construction of the claims at issue, the Court’s construction,~~ or the review and analysis of expert witnesses. Defendants reserve the right to amend and/or supplement these Invalidity Contentions based on 35 U.S.C. § 112 as discovery progresses.

Defendants offer these contentions in response to NovaPlast's Infringement Contentions and in light of the Court's *Markman* Order~~without prejudice to any position they may ultimately take as to any claim construction issues. To the extent the following contentions reflect constructions of claim limitations consistent with or implicit in NovaPlast's Infringement Contentions, no inference is intended nor should any be drawn that Defendants agree with any claim construction implied by NovaPlast's Infringement Contentions, and Defendants expressly reserve the right to contest such claim constructions.~~

Subject to the reservation of rights above, Defendants provide below an identification of asserted claims along with an identification of the specific limitations that are invalid pursuant to 35 U.S.C. § 112(b) as indefinite.

Defendants asserts that each asserted claim of the '213 Patent is invalid in that the '213 Patent specification fails to particularly point out and distinctly claim the alleged invention of the '213 Patent. Defendants further assert that each asserted claim of the '213 Patent is invalid as not containing a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the alleged invention.

Based on Defendants' present understanding of NovaPlast's infringement contentions, Defendants' assert that claims 1 and 5 of the '213 Patent are invalid as indefinite, not enabled, and/or lacking written description for reciting the following claim terms/phrases:

- "the distal end defining a longitudinal opening"
- "the distal end including a first longitudinal edge and a second longitudinal edge,"
- "the first longitudinal edge and second longitudinal edge further defining the longitudinal opening"
- "at least one first fastener"

These claim terms/phrases, the first three as apparently construed by NovaPlast and the fourth as construed by the Court, violate the written description, enablement, and/or definiteness requirements of 35 U.S.C. § 112.

Based on Defendants' present understanding of NovaPlast's infringement contentions, at least one or more of these claim terms/phrases are indefinite because they are inconsistent with and broader than the alleged invention disclosed in the specification and ~~given NovaPlast's apparent constructions of the claims~~, any person of ordinary skill in the art at the time of the invention would not understand what is claimed, even when the claims are read in light of the specification. Moreover, based on Defendants' present understanding of NovaPlast's infringement contentions, each of the asserted claims in which these claim terms/phrases appear lack written description because the specification of the '213 Patent demonstrates that the patentee neither conceived of nor demonstrated possession of all that NovaPlast now contends the claims cover.

For example, claim 1 which requires "the distal end defining a longitudinal opening" is invalid as being circular and inoperable and therefore indefinite. Specifically, claim 1 requires "a flexible elongated member defining a proximal end and a distal end," and then inconsistently requires "the distal end defining a longitudinal opening" [of the elongated member].

Furthermore, claim 1 which requires "the distal end including a first longitudinal edge and a second longitudinal edge," is invalid for being indefinite. As best understood, a distal end is simply an end, and therefore cannot define a "longitudinal opening" or include "the first longitudinal edge and the second longitudinal edge further defining the longitudinal opening," as claimed. Put another way, a distal end cannot define a longitudinal opening that is otherwise defined by first and second longitudinal edges because longitudinal edges are not the distal end. Furthermore, this plain claim language, "the distal end defining a longitudinal opening," and "the

distal end including a first longitudinal edge and a second longitudinal edge,” is not supported by the specification.

Moreover, the language “at least one first fastener” as construed by the Court to mean “one or more than one first fastener(s)” also lacks written description because the specification of the ‘213 Patent demonstrates that the patentee neither conceived of nor demonstrated possession of all that NovaPlast now contends the claims cover, namely, a device having only one first fastener. Indeed, conspicuously absent from the ‘213 Patent is any disclosure of a device having only one first fastener, much less a device “whereby a predetermined size distal opening is formed based on the engagement of the second fastener with the [[at least]] one first fastener, the distal opening sized to allow the prosthetic implant to be urged therethrough.” The bases for Defendants’ assertion that the language “at least one first fastener” violate the written description, enablement, and/or definiteness requirements of 35 U.S.C. § 112 are further articulated in Defendants’ Markman briefing (Dkts. 57, 59) and incorporated herein.

In addition, based on Defendants’ present understanding of NovaPlast’s infringement contentions, each of the asserted claims in which these claim terms/phrases appear are invalid because the specification fails to provide sufficient disclosure to enable any person of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to implement the invention without undue experimentation.

For at least the reasons set forth above, the claims fail to satisfy the requirements of § 112 ¶¶ 1 and 2. Moreover, that the proper construction of the claims is nonsensical and fails to satisfy 35 U.S.C. §§ 112 or 101 does not warrant judicial redrafting of the claims. *See e.g., Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 799 n.6 (Fed. Cir. 1990); *Chef Am.*,

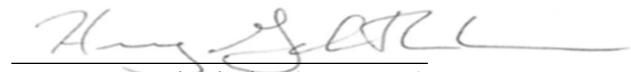
*Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004)(“Even a nonsensical result does not require the court to redraft the claims of the [patent].”).

**VI. ACCOMPANYING DOCUMENT PRODUCTION**

Pursuant to L. Pat. R. 3.4, Defendants previously produced ~~are producing~~ the prior art references set forth above at the following Bates numbers: INP0000001 to INP0000152, and ~~Defendants are producing~~ other documentation sufficient to show the operation, composition, or structure of any aspects or elements of Accused Product 1 and 2 at the following Bates numbers: INP0000153 to INP0000183. Defendants have ~~will also~~ made ~~make~~ available for inspection samples of the Accused Product 1 and 2.

Dated: August 24, 2023

Respectfully,



Henry A. Gabathuler (HG 6543)

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*Attorneys for Defendants*

## Exhibit 12

### U.S. Pat. No. 10,105,213 in view of U.S. Pat. No. 9,168,126 to Preissman (“Preissman ‘126”)

As described in detail below, Preissman ‘126 anticipates and/or renders obvious claims 1 and 5 of U.S. Patent No. 10,105,213 to Weinzwieg (the “‘213 Patent” or “Patent-in-Suit”), which was filed on December 29, 2015 and issued on October 23, 2018, (collectively, the “Asserted Claims”) under 35 U.S.C. § 102 and/or § 103, either alone or in combination with other prior art references, and/or in combination with the knowledge of a person of ordinary skill, as set forth in the following chart. Preissman ‘126 anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit as those claims have been applied by Plaintiff NovaPlast Corporation (“NovaPlast” or “Plaintiff”) in its Infringement Contentions and/or as construed by the Court in its [Markman] Opinion & Order dated July 26, 2023 (Dkt. 73) (the “Markman Order”)~~under Defendants’ understanding of the proper construction of the claims~~. To the extent it is found Preissman ‘126, or the additional references cited herein do ~~does~~ not expressly disclose certain limitations in the asserted claim, such limitations are inherent.

Preissman ‘126 was originally filed on Mar. 27, 2012, published as App. Pub. No. 2012/0185042 on Jul. 19, 2012, and issued on Oct. 27, 2015, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Preissman ‘126. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Preissman ‘126 (including product samples, and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Preissman ‘126 and/or its prior art status, as evidence that the technology described in Preissman ‘126 anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Zochowski was originally filed on Jun. 19, 2012 and published on Aug. 14, 2014, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Zochowski. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Zochowski (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Zochowski and/or its prior art status, as evidence that the technology described in Zochowski anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Ronsonet was originally filed on Nov. 8, 1990 and issued on Jan. 7, 1992, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Ronsonet. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology

described in Ronsonet (including product samples, and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Ronsonet and/or its prior art status, as evidence that the technology described in Ronsonet renders obvious the Asserted Claims of the Patent-in-Suit.

Fratti was originally filed on Jan. 31, 2007 and issued on Sept. 11, 2012, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Fratti. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Fratti (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Fratti and/or its prior art status, as evidence that the technology described in Fratti anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Guetty was originally filed on Jul. 16, 2004 and published on Feb. 15, 2007, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Guetty. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Guetty (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Guetty and/or its prior art status, as evidence that the technology described in Guetty anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

The cited portions of Preissman '126, Zochowski, Fratti, Guetty or Ronsonet are merely illustrative, and Defendants reserve the right to rely on alternative or additional evidence, including uncited portions of Preissman '126, Zochowski, Fratti, Guetty or Ronsonet. Where the chart below states that Preissman '126, Zochowski, Fratti, Guetty or Ronsonet "describes," "discloses," or "provides for" a limitation, such disclosure may be express, inherent, or implicit. If not anticipated, one or more claims of the Patent-in-Suit are rendered obvious in light of Preissman '126 alone or Preissman '126 in combination with Zochowski, Fratti, Guetty or Ronsonet or other prior art references and/or with the knowledge of a person of ordinary skill in the art.

This chart is subject to all reservations, objections, and disclaimers in Defendants' ~~Initial~~ Amended Invalidity Contentions and any amendment, supplement, or modification thereof, which are incorporated herein by reference in their entirety. Nothing stated herein shall be treated as an admission or suggestion that Defendants agree with NovaPlast regarding either the scope of the Asserted Claims or the claim constructions advanced by NovaPlast in its Infringement Contentions or anywhere else, or that any of Defendants' accused products meet any limitation of the Asserted Claims. ~~Nothing stated herein shall be construed as an admission or a waiver of any particular construction of any claim term.~~ Nothing stated herein shall be construed as an admission that the Asserted Claims are directed

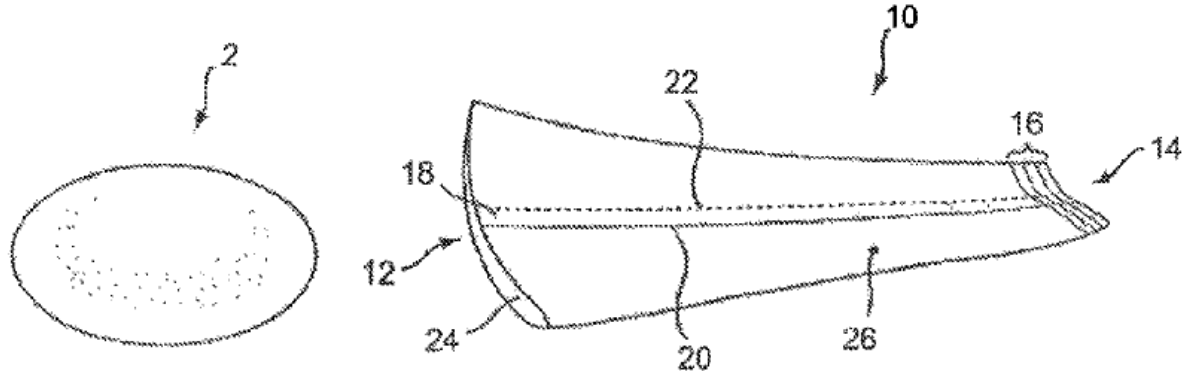


to patent-eligible subject matter. Defendants also reserve all rights to challenge any of the claim terms herein under 35 U.S.C. § 112, including by arguing that they are indefinite, not supported by the written description, and/or not enabled. Nothing stated herein shall be construed as an admission or waiver with respect to the effective filing date of the Asserted Claims.

**U.S. Pat. No. 10,105,213 in view of  
U.S. Pat. No. 9,168,126 to Preissman (“Preissman ‘126”)**

**CLAIM 1**

<b>Asserted Claim 1 of the ‘213 Patent</b>	<b>Exemplary Citations to Preissman ‘126</b>
<p>[1.p] 1. A delivery system adapted to facilitate insertion of a prosthetic implant through a surgical opening, the system comprising:</p>	<p>To the extent the preamble is limiting, Preissman ‘126 discloses this limitation:</p> <p style="padding-left: 40px;">A tapered sleeve is provided for implant delivery. An implant (e.g., a pre-filled silicone breast implant) is introduced into a large proximal end of the sleeve and extruded into a surgical pocket of minimal access incision size through a small-sized distal end of the device. Sized appropriately to the implant, the sleeve remains intact during implant run-through of the sleeve.</p> <p>Preissman ‘126, Abstract.</p>
<p>[1.1] a flexible elongated member defining a proximal end and a distal end, the proximal end formed opposite the distal end and defining a closed end, the distal end defining a longitudinal opening;</p>	<p>Preissman ‘126 discloses this limitation:</p> <p style="padding-left: 40px;">Like the original Keller device, the present invention comprises a truncated conical sleeve. The frustum-shaped device is adapted to receive a silicone breast implant and by squeezing the sleeve and expelling the implant from its smaller end into a tissue pocket. The implant delivery sleeve is constructed of a flexible fabric and similar in size to store-bought pastry bags.</p> <p style="padding-left: 40px;">More specifically, since the size of silicone implants may vary in a range from about 150 cc to about 800 cc, the dimensions of the sleeve may vary. A proximal opening sized to fit any implant in this size range and a distal opening sized to fit the smallest implant may be desirable.</p> <p>Preissman ‘126, 1:65-2:9.</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Preissman '126
	 <p data-bbox="1207 824 1318 873" style="text-align: center;">Fig. 1</p> <p data-bbox="678 906 982 938">Preissman '126, FIG. 1.</p> <p data-bbox="735 995 1837 1133">FIG. 1 illustrates a pre-filled silicone implant 2 and sleeve 10 according to the present invention provided to facilitate implant delivery. Sleeve 10 has general conical shape that defines a first opening 12 at a larger end and a smaller opening 14 at a terminal end.</p> <p data-bbox="678 1157 997 1190">Preissman '126, 3:16-20.</p> <p data-bbox="735 1247 1837 1417">Sleeve 10 is advantageously constructed with a seam 18 formed using double-sided tape to close overlapping edges 20, 22 of a cut sheet. Of course, other joining methods (e.g., ultrasonic welding), and/or constructional approaches may be employed. Seam 18 may have a gap or break (e.g., between sections of the tape, as indicated by a dashed line) in it to provide a friable safety feature. The tape may terminate proximal of the</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Preissman '126
	<p>distal end for the same purpose.</p> <p>Preissman '126, 3:33-40.</p> <p>With the implant set within the sleeve, the sleeve body 26 may be twisted closed.</p> <p>Preissman '126, 6:14-15.</p> <div data-bbox="751 537 1598 829"> </div> <p>Fig. 2A                      Fig. 2B</p> <p>Preissman '126, Figs. 2A and 2B show the closed end nature of the twisted sleeve. Preissman '126, Col. 6: 14-15 (“With the implant set within the sleeve, the sleeve body 26 may be twisted closed.”)</p>
<p>[1.2] the distal end including a first longitudinal edge and a second longitudinal edge, the first longitudinal edge and second longitudinal edge further defining the longitudinal opening,</p>	<p>Preissman '126 discloses this limitation:</p> <p>FIG. 1 illustrates a pre-filled silicone implant 2 and sleeve 10 according to the present invention provided to facilitate implant delivery. Sleeve 10 has general conical shape that defines a first opening 12 at a larger end and a smaller opening 14 at a terminal end.</p> <p>Preissman '126, 3:16-20.</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Preissman '126
	<p>Sleeve 10 is advantageously constructed with a seam 18 formed using double-sided tape to close overlapping edges 20, 22 of a cut sheet.</p> <p>Preissman '126, 3:33-35.</p>
<p>[1.3] at least one first fastener formed on the elongated member adjacent the first longitudinal edge,</p> <p>and a second fastener formed on the elongated member adjacent the second longitudinal edge;</p> <p>[1.4] the second fastener adapted to matingly engage with the at least first fastener and to close the longitudinal opening,</p>	<p>Preissman '126 discloses this limitation:</p> <p>Sleeve 10 is advantageously constructed with a seam 18 formed using double-sided tape to close overlapping edges 20, 22 of a cut sheet. Of course, other joining methods (e.g., ultrasonic welding), and/or constructional approaches may be employed. Seam 18 may have a gap or break (e.g., between sections of the tape, as indicated by a dashed line) in it to provide a friable safety feature. The tape may terminate proximal of the distal end for the same purpose.</p> <p>Preissman '126, 3:33-40.</p> <p>To the extent NovaPlast alleges that this limitation is not expressly or inherently disclosed in Preissman '126, it would have been obvious in light of the knowledge of a person of ordinary skill in the art. A person of ordinary skill in the art would have been motivated to combine Preissman '126 with any of the other references identified in <del>Defendants' Initial Invalidation Contentions regarding the '213 Patent below</del> at least to the extent they desired to provide a device with an elongated member having a longitudinal opening including first and second fasteners formed on respective edges of the elongated member and adapted to matingly engage to close the longitudinal opening.</p> <p>For example, at least the references listed below disclose a flexible elongated member having a longitudinal opening including first and second fasteners formed on respective edges of the elongated member and adapted to matingly engage to close the opening.</p> <p>U.S. Pat. No. 5,121,779 to Green ("Green"), Exhibit 1 at 1.3-1.4.</p> <p>U.S. Pat. App. Pub. No. 2014/0228951 to Zochowski ("Zochowski"), Exhibit 32 at 1.3-1.4.</p> <p>U.S. Pat. App. Pub. No. 2015/0032208 to Priessman ("Priessman '208"), Exhibit 4 at 1.3-1.4.</p> <p>U.S. Pat. No. 5,078,189 to Ronsonet ("Ronsonet"), Exhibit 45 at 1.3-1.4.</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Preissman '126
	<p>U.S. Pat. No. 4,651,504 to Bentsen ("Bentsen"), Exhibit 6 at 1.3-1.4.  U.S. Pat. No. 8,690,428 to Kruse ("Kruse"), Exhibit 8 at 1.3-1.4.  U.S. Pat. No. 8,262,289 to Fratti ("Fratti"), Exhibit 69 at 1.3-1.4.  U.S. Pat. App. Pub. No. 2007/0038310 to Guetty ("Guetty"), Exhibit 710 at 1.3-1.4.</p> <p><u>For example, to the extent NovaPlast alleges that this limitation and the longitudinal opening limitation of [1.1] and [1.2] are not expressly or inherently disclosed in Priessman '126, it would have been obvious in light of Guetty and the knowledge of a person of ordinary skill in the art.</u></p> <p><u>[0099] Sheath 5 is fitted with at least one lateral opening 6 arranged over all or part of its length. Said lateral opening 6 may extend, as shown in FIG. 1, essentially longitudinally over the length of sheath 5. It is altogether conceivable, without on this account leaving the framework of the invention, that this lateral opening 6 might extend in any other way, and for example transversally or helically. Said lateral opening 6 is closed by locking means 4 when case 2 is in the closed configuration (FIG. 1), said lateral opening 6 being opened up, in order to make possible the deformation of implant 1 into its functional configuration, when case 2 is in the open configuration (not shown).</u></p> <p><u>Guetty, [0099].</u></p> <p><u>According to another alternative exemplary embodiment, locking means 4 can be formed from a "Ziplock®" zipper system, said zipper making possible the opening or closing of case 2, and being to this end linked to a traction thread forming opener member 3.</u></p> <p><u>Guetty [0146]</u></p> <p><u>To the extent that Priessman '128's disclosure of a using double-sided tape to close overlapping edges 20, 22 of a cut sheet, other joining methods (e.g., ultrasonic welding),</u></p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Priessman '126
	<p>and/or constructional approaches (Priessman '126, 3:33-40), for closing the longitudinal edge of a device used to extrude the implant into the tissue pocket, one skilled in the art would be motivated to combine Priessman '126 according to Guetty so as to utilize opposed mating structures such as a zip-loc fastener to join the opposing longitudinal edges of Priessman '126's funnel/sheet, because as disclosed in Guetty, such a longitudinal aperture and closure was one of a limited number of known configurations that could be successfully used for closing (or opening) devices for delivering implants into a tissue pocket of a patient of the type described in Priessman '126. Making such a change would have resulted in nothing more than the simple substitution of one known type of fastener construction (e.g., double sided tape, other joining methods and constructional approaches) for another (e.g., two opposing complementary zip-loc structures) and there is a reasonable expectation that the use of a zip-loc closure system would be successful and would result in an enhanced and successful device because it was known in the art that such fasteners were known from Guetty for use in implant delivery devices and would allow for a sterile and secured device for delivery an implant out of the distal opening into the tissue pocket while preserving the sterile environment. Guetty, [0099]. Therefore, combining the teachings of Priessman '126 and Guetty is a simple substitution of a known element for another according to known methods that does no more than yield a predicable result, and also would be obvious to try given the limited number of fasteners known to be suitable for closing a longitudinal aperture of an implant delivery device with a reasonable expectation of success, and in such case such a combination is obvious. For at least the foregoing reasons, such a modification would render obvious a distal opening defining the longitudinal opening as recited in [1.1]-[1.2].</p> <p>For at least the reasons noted below with respect to claim 5, combining Priessman '126 with Ronsonet would similarly obviate this limitation of claim 1. See discussion of Ronsonet in connection with claim 5, below.</p>
[1.5] whereby a predetermined size distal opening is formed based on the engagement of the second fastener with the at least one first fastener, the	<p>Priessman '126 discloses this limitation:</p> <p>Other constructional features define another optional aspect of the present invention. Specifically, the device is advantageously cut from rip-stop nylon cloth that is adhered</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Preissman '126
<p>distal opening sized to allow the prosthetic implant to be urged therethrough.</p>	<p>along an overlapping seam with double-sided tape 3M, Inc. offers 5 mill transfer tape that is suitable for this purpose; suitable fabric may be obtained from Challenge Sailcloth, Inc. So constructed, no binding of the fabric edges is required to prevent unraveling or other problems. Cost is utterly minimized, without any compromise in performance.</p> <p>In fact, definite performance advantages can be realized with this construction. Namely, for constructions in which the sleeve fabric remains unbound at the distal end of the sleeve, the approach offers an inherent safety feature. Sized appropriately to the implant, the distal end of the sleeve remains intact and the implant delivered without incident. However, if the end of the sleeve is undersized relative to the implant (to, the extent that damage might occur to the implant if it were forced through the sleeve), the sleeve is configured so that the end of the sleeve fails (i.e., tears, rips or splits) instead. The configuration, specifically, is one in which the end of the sleeve is unreinforced along the cut edge of the aforementioned "rip-stop" fabric.</p> <p>...</p> <p>If the end of the sleeve is not large enough relative to the implant (as originally provided and/or as-trimmed), the fabric (or associated feature) will tear, open or otherwise separate, relieving the stress on the implant being pushed through the distal end opening/aperture of the sleeve. As a result, the implant will be undamaged despite the aggressive use to which it has been subjected. Indeed, extensive testing has proven that implants are generally not damaged when the sleeve is so undersized and such a safety feature is included in the sleeve.</p> <p>Note, however, that such aggressive use does not necessarily connote misuse. Given experience and developing a certain feel for use of the device, physicians may choose to size the distal opening of the sleeve relatively smaller. (Even smaller than recommended by the guide and training provided by the assignee hereof.) The reason for such action may be to absolutely minimize the size of incision through which an implant is placed. Regardless of the reason, both the patient and surgeon are protected</p>



Asserted Claim 1 of the '213 Patent	Exemplary Citations to Preissman '126
	<p>from becoming overly aggressive in this regard by means of the fail-safe feature of the present invention.</p> <p>Preissman '126, 2:44-3:37.</p> <p>Another type of fail-safe approach is contemplated as well. Specifically, it operates proximal to the distal end of the device. Although physicians may be instructed to run an implant through the device prior to attempting delivery into a patient tissue pocket, the physician may not actually do so. As a result, the above-described features may not operate because the margin of the tissue pocket can provide adequate support to the sleeve so that it will not rip under unacceptable implant fit situations.</p> <p>A solution to this problem, then, is to provide a friable feature proximal to the insertion depth of the delivery device. This feature may be discrete/isolated along the length of the sleeve. The feature may comprise an axial and/or longitudinal slit(s) or perforation of the sleeve material, a gap in the tape (if used) to seal the edges of the sleeve or other means. For example, localized weakening of the material can alternatively be accomplished by conditioning the material. The conditioning may comprise an acid etch or exposure to laser, plasma or other energy that results in a change in the properties of the base material.</p> <p>In another approach, the safety feature runs the length of the sleeve. In which case, the feature may be the bonding tape, with a bond strength selected to fail in shear at a given threshold. Another approach utilizes perforations running the length of the delivery device. Further options are possible as well, as above.</p> <p>Preissman '126, 3:45-4:3.</p> <p><u>To the extent NovaPlast alleges that this limitation is not expressly or inherently disclosed in Priessman '126, it would have been obvious in light of the knowledge of a person of ordinary skill in the art. A person of ordinary skill in the art would have been motivated to combine</u></p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Preissman '126
	<p><u>Priessman '126 with any of the other references identified below at least to the extent they desired to provide a device with a longitudinal opening that is closed by a first and second fastener, whereby engagement of the first and second fasteners forms a predetermined size distal opening that is sized to allow a prosthetic implant to be urged therethrough.</u></p> <p><u>More specifically, at least the references listed below disclose a device with a longitudinal opening that is closed by a first and second fastener, whereby engagement of the first and second fasteners forms a predetermined size distal opening that is sized to allow or is capable of allowing a prosthetic implant to be urged therethrough.</u></p> <p><u>U.S. Pat. No. 5,078,189 to Ronsonet ("Ronsonet"), Exhibit 4 at 1.5.</u>  <u>U.S. Pat. App. Pub. No. 2007/0038310 to Guetty ("Guetty"), Exhibit 7 at 1.5.</u></p> <p><u>For example, Priessman '126 discloses that the distal end aperture of its device may be sized to allow the implant to be urged therethrough. See e.g., Priessman '126, 2:44-3:37. Thus, the modification of Priessman '126 in view of Guetty, which as discussed above with respect to [1.2]-[1.4] discloses a longitudinal opening that can be opened or closed using, e.g., a zip-loc type of opposing fasteners, would result in a structure in which engagement of the first fastener with the second fastener to close the longitudinal opening would necessarily form a distal opening of a predetermined size, particularly, a size that allows an implant to be urged therethrough. Therefore, combining the teachings of Priessman '126 and Guetty is a simple substitution of a known element for another according to known methods that does no more than yield a predictable result. For at least the reasons noted below with respect to claim 5, combining Priessman '126 with Ronsonet would similarly obviate this limitation of claim 1. See discussion of Ronsonet in connection with claim 5, below.</u></p> <p>The intended use of the device of claim 1, the type of object for insertion, and the size of the object are not material limitations.</p>

**CLAIM 5**

<b>Asserted Claim of the '213 Patent</b>	<b>Exemplary Citations to Preissman '126 <u>in view of Ronsonet</u></b>
<p>[5.0] 5. The delivery system of claim 1, each of the at least one first, fastener further comprising a channel, the second fastener defining a shoulder, the shoulder adapted to be received within and secured with the channel of at least one of the first fasteners.</p>	<p><u>This limitation is met.</u></p> <p>Preissman '126 discloses <del>this</del> the system of claim 1, from which this claim 5 depends, for the reasons stated above. <del>limitation:</del></p> <p>To the extent NovaPlast alleges that this limitation is not expressly or inherently disclosed in Preissman '126, it would have been obvious in light of the knowledge of a person of ordinary skill in the art. A person of ordinary skill in the art would have been motivated to combine Preissman '126 with any of the other references identified in <del>Defendants' Initial Invalidation Contentions regarding the '213 Patent</del> below at least to the extent they desired using a <u>plurality of first fasteners</u> <del>fastener</del> comprising a channel and a fastener comprising a shoulder that is received and secured within <del>the</del> <u>a</u> channel.</p> <p>For example, at least the references listed below disclose a device with an opening that is closed by <del>a</del> <u>a plurality of first fasteners</u> comprising a channel and a second fastener comprising a shoulder, the shoulder adapted to be received within and secured with <del>the</del> <u>a</u> channel of <del>the</del> <u>a</u> first fastener.</p> <p>U.S. Pat. No. 5,121,779 to Green ("Green"), Exhibit 1 at 5.0.  U.S. Pat. App. Pub. No. 2014/0228951 to Zochowski ("Zochowski"), Exhibit <del>23</del> at 5.0.  U.S. Pat. No. 5,078,189 to Ronsonet ("Ronsonet"), Exhibit <del>45</del> at 5.0.  U.S. Pat. No. 4,651,504 to Bentsen ("Bentsen"), Exhibit 6 at 5.0.  U.S. Pat. No. 8,690,428 to Kruse ("Kruse"), Exhibit 8 at 5.0.  U.S. Pat. No. 8,262,289 to Fratti ("Fratti"), Exhibit <del>96</del> at 5.0.  U.S. Pat. App. Pub. No. 2007/0038310 to Guetty ("Guetty"), Exhibit <del>107</del> at 5.0.</p> <p><u>More specifically, Ronsonet discloses the limitations of claim 5:</u></p> <p><u>What is provided is an apparatus which includes a rectangular sheet of flexible plastic, the first face of the sheet which includes a plurality of parallel spaced apart channels, and on the second face of the sheet including a pair of raised members, one raised</u></p>

Asserted Claim of the '213 Patent	Exemplary Citations to Preissman '126 <u>in view of Ronsonet</u>
	<p><u>member positioned substantially along a first edge of the sheet, and the second raised member positioned substantially perpendicular thereto along the bottom edge of the sheet, so that when the sheet is configured into a funnel shape, one of the raised locking members is mated into the channel members, to form a sealed juncture thereon, and for defining a sealed cone having an enlarged upper end and a reduced lower spout end, defining an overall funnel member.</u></p> <p><u>Ronsonet, 1:64-2:9</u></p> <p><u>With that locking concept in mind, reference is made now to FIGS. 3 and 4 of the apparatus, which illustrates the manner in which the apparatus is configured into a shape to function as an adjustable funnel apparatus 50 as illustrated in FIG. 4. It is quite commonplace that if one takes a substantially rectangular sheet as illustrated in FIGS. 1 and 2, that if one were to configure the positioning of the sheet as illustrated in FIG. 3, by rotating one face of the sheet in a circular fashion, that the sheet could be configured into a funnel apparatus as illustrated in FIG. 4. With that general concept in mind which is quite commonly known, reference is made to FIG. 3 where it is seen that the edge 18 of the apparatus has been formed into a circular pattern in the direction of arrow 40, and face 22 having the plurality of channel members 28 is being circulated around so that one of the parallel channel members 28 is brought into parallel locking alignment with horizontal raised locking member 38, and horizontal channel member 34 is brought into parallel locking alignment with vertical raised locking member 36 along edge 20, as illustrated in phantom view in FIG. 4. Therefore, once the locking members have been pressed into locking relationship as with a ZIPLOCK® locking arrangement, FIG. 4 would define the funnel member 50 having an upper enlarged spout area 52, a continuous annular wall portion 54 which is then sealed along a common edge 56 via locking members 28, 38 and sealed along a top edge 58 via the locking relationship of locking members 34, 36. Further, as illustrated there would be further defined a reduced downspout opening 60 which is formed as a result of the manner in which the rectangular sheet 12 is placed into the configuration as illustrated.</u></p> <p><u>Turning now to the plurality of channel members 28 as they would configure into</u></p>

Asserted Claim of the '213 Patent	Exemplary Citations to Preissman '126 <u>in view of Ronsonet</u>
	<p><u>locking relationship with raised members 34, 36, as was discussed earlier, each of the channel members 28 are positioned in parallel relationship for defining a specific dimensional distance therebetween. Therefore, this dimensional distance as defined by the letter A in FIG. 3, results in a particular configuration of the diameter of downspout 60. There fore, as raised locking edge 38 is configured into locking engagement with a particular channel 28, the diameter of the downspout 60 formed thereby is of a dimension in direct relation to the change in the distance between the parallel channels 28. For example, if one were to assume that the diameter of downspout 60 in FIG. 4 is inch in the position that locking channel 28 locks with raised locking member 38, then were locking member 38 moved to the next channel 28B, as illustrated in FIG. 4, if that distance would be for example of an inch, then the diameter of the downspout 60 would be reduced of an inch. Therefore, with this relationship in mind, it is foreseen that the plurality of channels 28 allow one therefore to matingly engage a particular channel 28 with locking member 38, depending on the diameter of downspout 60 that one wishes to achieve in the final configuration of funnel member 50.</u></p> <p><u>Ronsonet, 3:51-4:41.</u></p>

Asserted Claim of the '213 Patent	Exemplary Citations to Preissman '126 <u>in view of Ronsonet</u>
	<div data-bbox="682 284 1753 771"> </div> <p data-bbox="682 812 955 844"><u>Ronsonet, FIG. 3 – 4.</u></p> <p data-bbox="724 901 1837 1193"><u>It should be fully understood that this particular embodiment should not be limiting in the sense that the plurality of channel member 28 do not necessarily have to be evenly spaced apart, but could be configured into a particular dimensional arrangement i.e. one inch apart or even having a plurality of channel members along face 22 which would allow one to configure the funnel in a single funnel size, or in two or three or more funnel sizes depending on the location of the channel members 28. Therefore, it is foreseen that the sheets could be formed in many configurational sizes, and not limited to the sizes as illustrated in the Figures.</u></p> <p data-bbox="682 1209 924 1242"><u>Ronsonet, 4:42-53.</u></p> <p data-bbox="724 1299 1323 1331"><u>1. An adjustable funnel apparatus comprising:</u></p> <p data-bbox="724 1364 1743 1396"><u>a) a substantially flexible sheet member, having a first face and a second face;</u></p>

Asserted Claim of the '213 Patent	Exemplary Citations to Preissman '126 <u>in view of Ronsonet</u>
	<p><u>b) at least one first channel running substantially along the width of said first face;</u></p> <p><u>c) a second channel running along a portion of the length of the first face and substantially perpendicular to the positioning of the at least one first channel;</u></p> <p><u>d) a first raised locking member running along adjacent an edge of the second face of the sheet member;</u></p> <p><u>e) a second raised locking member running along the lower edge of the second face and substantially perpendicular to the alignment of the first locking member;</u></p> <p><u>f) means for positioning the sheet member into a configuration so that one of the at least one first channel lockingly mates with the second raised locking member and the second channel mates with the first locking member, for defining a funnel shaped apparatus sealed by the locking engagement of one of the at least one first channel and the second channel to the second and first locking members respectively.</u></p> <p><u>Ronsonet, claim 1, 4:62-5:18.</u></p> <p><u>One skilled in the art would be motivated to modify Preissman '126 according to Ronsonet to utilize a plurality of first fasteners on one longitudinal edge of the elongated sleeve and a complementary second fastener on the opposing longitudinal edge of the elongate sleeve which one selected first fastener and second fastener can be matingly engaged for form a locked seal along the longitudinal edge and thereby define the size of the distal opening.</u></p> <p><u>Priessman '126 recognizes that dispensing devices including funnels, such as pastry bags or Ronsonet's funnel, are analogous art to implant delivery devices. One of ordinary skill in the art would have been motivated to consider the techniques taught by such dispensing devices and existing implant delivery devices to arrive at the alleged invention of the Asserted Claims.</u></p> <p><u>The Keller filing describes a device and methods addressing each of the above-referenced issues. It discloses a specially-adapted pastry bag type device for implant</u></p>

Asserted Claim of the '213 Patent	Exemplary Citations to Preissman '126 <u>in view of Ronsonet</u>
	<p><u>introduction. The device enables silicone implant insertion though smaller incisions at dramatically reduced introduction time as compared to the common practice for silicone implant introduction. Likewise, the potential for implant damage has been significantly reduced.</u></p> <p><u>Priessman '126, 1:48-56.</u></p> <p><u>Priessman '126 recognizes the problem of having to construct a truncated, generally conical sleeve to be squeezed to expel pre-filled, solid, and/or semi-solid implants through the smaller distal end into a tissue pocket, wherein at least the silicone implants vary in range from 150 cc to about 800 cc and the dimension of the sleeve may vary. Priessman '126, 1:65-2:9.</u></p> <p><u>Ronsonet recognizes this same problem for funnels (i.e., a truncated, generally conical sleeve made of a flexible plastic material) that have to be provided with different sized distal end openings according to the specific environment in which it will be used, and proposes an alternative solution that allows the user to select the size of the distal opening 60 through the implementation of a plurality of spaced apart raised members 36, 38 along one longitudinal edge of the sleeve, and a complementary fastener of channel members 28, 34 on the opposing longitudinal edge of the sleeve, wherein the selection of different ones of the raised members to mate with the opposing channel members along their entire length to form a “ziplocked” seal closing that longitudinal edge will result in different sized distal openings 60 according to the distances between the different ones of the plurality of raised channels 36, 38. (Ronsonet Col. 3, line 34 - Col. 4, line 41). Ronsonet also discloses that this solution has the advantage of providing a single product that can be sized by the user to have the desired sized distal opening for the environment of use and reduced size for storage when not in use. (Ronsonet Col. 1, lines 25-44).</u></p> <p><u>One skilled in the art would be motivated to make the substitution because an adjustable funnel having a longitudinal seal formed by the locking raised members and opposing channels would allow for improved scale and efficiency in manufacturing and reduced inventory in having a device with adjustable dimensions rather than stocking multiple different sized devices, and improved efficiency in use by allowing the user to select the size, and if the initial size was</u></p>



Asserted Claim of the '213 Patent	Exemplary Citations to Preissman '126 <u>in view of Ronsonet</u>
	<p><u>incorrect then the “ziplocked” seam could be unlocked and a different channel selected and the seam relocked at the correct size, whereas in the Priessman '208 disclosure the sleeve having too large a distal opening or a distal opening not cut cleanly would have to be discarded and a new sleeve, and there is a reasonable expectation that the substitution would be successful and would result in a sleeve having adjustable dimensions to established the proper sized distal opening for the implant to be delivered therethrough into the tissue pocket. One skilled in the art would understand that this substitution could be implemented successfully without impacting the need for preserving the sterile environment of the Priessman '208 device.</u></p> <p><u>Therefore, combining the teachings of Preissman '208 and Ronsonet is a combination of familiar elements according to known methods that does no more than yield a predicable result, and such a combination is obvious.</u></p> <p><u>By way of further example, Fratti discloses first fasteners comprising a plurality of channels on one side of a bag opening and one or more protrusions on the opposing side of the bag opening that are configured to matingly engage to close the opening. See e.g., Fratti, Exhibit 6, 5.0.</u></p> <p><u>Similarly, both Guetty and Zochowski disclose a closure mechanism for a second opening of an implant delivery device that can comprise a ziploc type of closure. See e.g., Guetty, Exhibit 7 at 5.0; Zochowski, Exhibit 2 at 5.0. As would be known by a person of ordinary skill in the art, ziploc type closures can comprise one or more channels provided on one side of a bag opening and one or more complementary shaped structures (e.g., protrusions) provided on an opposing side of the opening that can be matingly engaged.</u></p>

## Exhibit 32

### U.S. Pat. No. 10,105,213 in view of U.S. Pat. App. Pub. No. 2014/0228951 to Zochowski (“Zochowski”)

As described in detail below, Zochowski anticipates and/or renders obvious claims 1 and 5 of U.S. Patent No. 10,105,213 to Weinzweig (the “’213 Patent” or “Patent-in-Suit”), which was filed on December 29, 2015 and issued on October 23, 2018, (collectively, the “Asserted Claims”) under 35 U.S.C. § 102 and/or § 103, either alone or in combination with other prior art references, and/or in combination with the knowledge of a person of ordinary skill. Zochowski anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit as those claims have been applied by Plaintiff NovaPlast Corporation (“NovaPlast” or “Plaintiff”) in its Infringement Contentions and as construed by the Court in its [Markman] Opinion & Order dated July 26, 2023 (Dkt. 73) (the “Markman Order”)/or under Defendants’ understanding of the proper construction of the claims. To the extent it is found Zochowski does not expressly disclose certain limitations in the asserted claim, such limitations are inherent.

Zochowski was originally filed on Jun. 19, 2012 and published on Aug. 14, 2014, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Zochowski. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Zochowski (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Zochowski and/or its prior art status, as evidence that the technology described in Zochowski anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Preissman ‘126 was originally filed on Mar. 27, 2012, published as App. Pub. No. 2012/0185042 on Jul. 19, 2012, and issued on Oct. 27, 2015, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Preissman ‘126. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Preissman ‘126 (including product samples, and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Preissman ‘126 and/or its prior art status, as evidence that the technology described in Preissman ‘126 anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Priessman ‘208 was originally filed on Aug. 11, 2014 and published on Jan. 29, 2015, and is a continuation of application No. PCT/US12/24917 which published as WO2013122568 on Aug. 22, 2013, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Priessman ‘208. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the

technology described in Priessman '208 (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Priessman '208 and/or its prior art status, as evidence that the technology described in Priessman '208 anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Ronsonet was originally filed on Nov. 8, 1990 and issued on Jan. 7, 1992, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Ronsonet. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Ronsonet (including product samples, and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Ronsonet and/or its prior art status, as evidence that the technology described in Ronsonet renders obvious the Asserted Claims of the Patent-in-Suit.

Kruse was originally filed on Nov. 12, 2009 and issued on Apr. 8, 2014, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Kruse. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Kruse (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Kruse and/or its prior art status, as evidence that the technology described in Kruse anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Fratti was originally filed on Jan. 31, 2007 and issued on Sept. 11, 2012, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Fratti. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Fratti (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Fratti and/or its prior art status, as evidence that the technology described in Fratti anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Guetty was originally filed on Jul. 16, 2004 and published on Feb. 15, 2007, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Guetty. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Guetty (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or

additional documents concerning the structure, function, operation, and/or features of the technology described in Guetty and/or its prior art status, as evidence that the technology described in Guetty anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

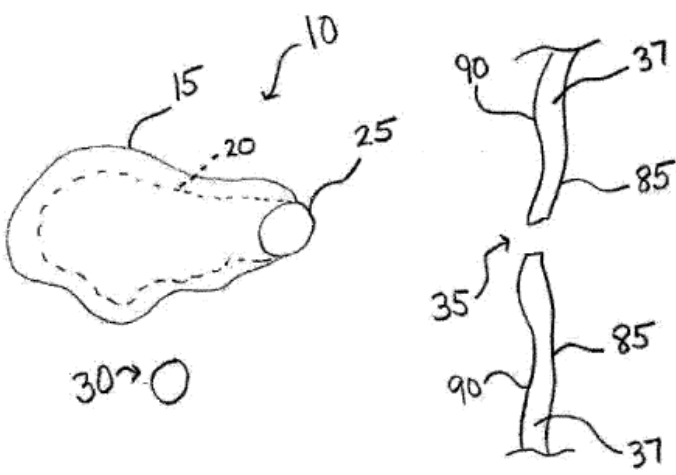
The cited portions of Zochowski, Ronsonet, Priessman '126, Priessman '208, Kruse, Fratti and Guetty are merely illustrative, and Defendants reserve the right to rely on alternative or additional evidence, including uncited portions of Zochowski. Where the chart below states that Zochowski, Ronsonet, Priessman '126, Priessman '208, Kruse, Fratti or Guetty “describes,” “discloses,” or “provides for” a limitation, such disclosure may be express, inherent, or implicit. If not anticipated, one or more claims of the Patent-in-Suit are rendered obvious in light of Zochowski alone or Zochowski in combination with Ronsonet, Priessman '126, Priessman '208, Kruse, Fratti or Guetty or other prior art references and/or with the knowledge of a person of ordinary skill in the art.

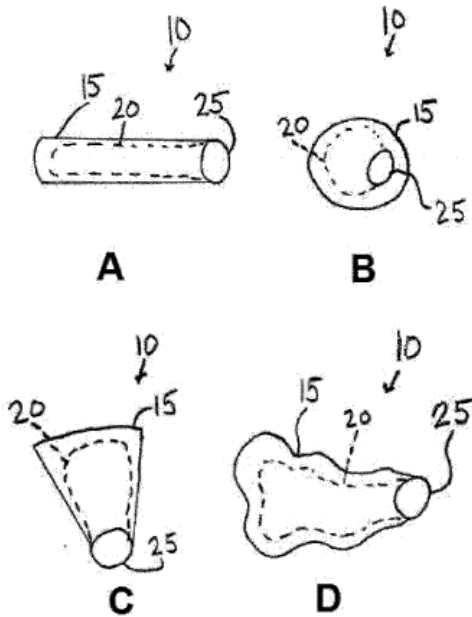
This chart is subject to all reservations, objections, and disclaimers in Defendants' ~~Initial~~ Amended Invalidity Contentions and any amendment, supplement, or modification thereof, which are incorporated herein by reference in their entirety. Nothing stated herein shall be treated as an admission or suggestion that Defendants agree with NovaPlast regarding either the scope of the Asserted Claims or the claim constructions advanced by NovaPlast in its Infringement Contentions or anywhere else, or that any of Defendants' accused products meet any limitation of the Asserted Claims. ~~Nothing stated herein shall be construed as an admission or a waiver of any particular construction of any claim term.~~ Nothing stated herein shall be construed as an admission that the Asserted Claims are directed to patent-eligible subject matter. Defendants also reserve all rights to challenge any of the claim terms herein under 35 U.S.C. § 112, including by arguing that they are indefinite, not supported by the written description, and/or not enabled. Nothing stated herein shall be construed as an admission or waiver with respect to the effective filing date of the Asserted Claims.

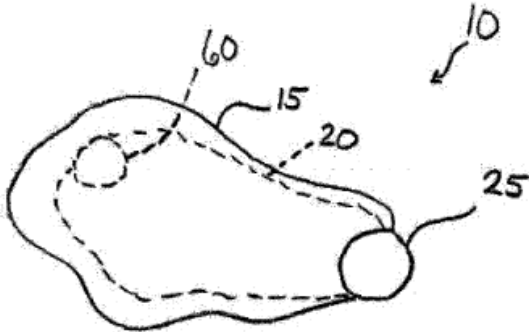
**U.S. Pat. No. 10,105,213 in view of  
U.S. Pat. Pub. No. 2014/0228951 to Zochowski (“Zochowski”)**

**CLAIM 1**

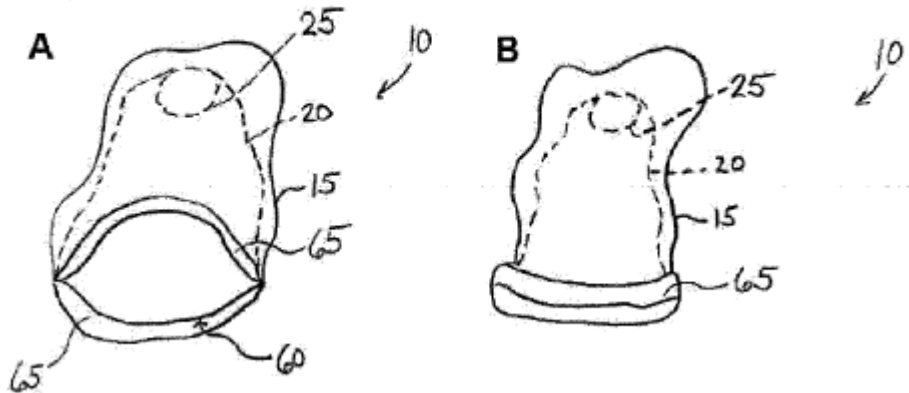
<b>Asserted Claim 1 of the ‘213 Patent</b>	<b>Exemplary Citations to Zochowski</b>
<p>[1.p] 1. A delivery system adapted to facilitate insertion of a prosthetic implant through a surgical opening, the system comprising:</p>	<p>To the extent the preamble is limiting, Zochowski discloses this limitation:</p> <p style="padding-left: 40px;">The present invention generally relates to an implant insertion device, and particularly, to a breast implant insertion device and method of using thereof. The present invention is related to surgical delivery of an implant. In particular, the invention describes a device for the delivery of a breast implant that avoids contact with the skin reducing potential sources of incidental infection.</p> <p>Zochowski, Abstract.</p> <p style="padding-left: 40px;"><u>[0073] The device 10 may be used for the insertion of a breast implant into a surgical pocket formed in the patient.</u></p> <p><u>Zochowski, [0073].</u></p>
<p>[1.1] a flexible elongated member defining a proximal end and a distal end, the proximal end formed opposite the distal end and defining a closed end, the distal end defining a longitudinal opening;</p>	<p>Zochowski discloses this limitation:</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Zochowski
	<p style="text-align: center;"><b>FIGURE 1</b></p>  <p>[0072] As shown in FIG. 1, an implant insertion device 10 (hereinafter referred to as the “device 10”) is provided comprising a body 15 defining a cavity 20 therein that is accessible via an aperture 25. An implant 30 is positionable in the cavity 20 and the aperture 25 is substantially coaxially alignable with an incision 35 in the tissue 37 of a human or animal (hereinafter referred to as the “patient”) for insertion of the implant 30 therein.</p> <p>Zochowski, [0072].</p> <p>[0074] The body 15 may be provided in a variety of shapes and materials. In the non-limiting examples as shown in FIG. 2A-D, the body 15 may be substantially cylindrical, spherical, funnel shaped, or bag-like. The body 15 may be comprised of metal, polymers or plastics, composites, and combinations thereof, and may be covered with a friction reducing coating to minimize trauma to the implant 30 and the tissue 37.</p>

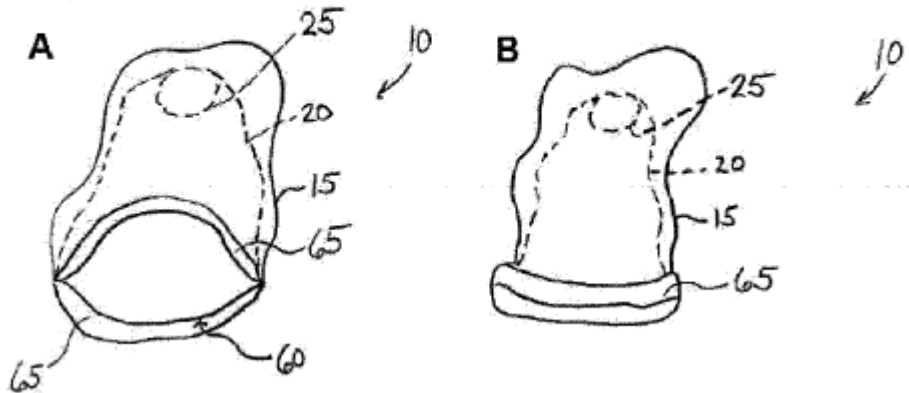
Asserted Claim 1 of the '213 Patent	Exemplary Citations to Zochowski
	<p>...</p> <p>[0075] The cavity 20 may extend a portion of or the entire length of the body 15. In an embodiment, at least a portion of the body 15 is flexible and capable of allowing a user 200, such as a physician, to manipulate or otherwise apply pressure to the implant 30 via the body 15 when positioned in the cavity 20 by hand or with an instrument to transfer the implant 30 from the cavity 20 and into the patient via the incision 35.</p> <p>Zochowski, [0074]-[0075].</p> <p><b>FIGURE 2</b></p>  <p>Zochowski, FIG. 2. <u>In at least the elongated device embodiment shown in FIG. 1, 2C-2D, the proximate end is closed and an aperture 25 is located at the distal end.</u></p>

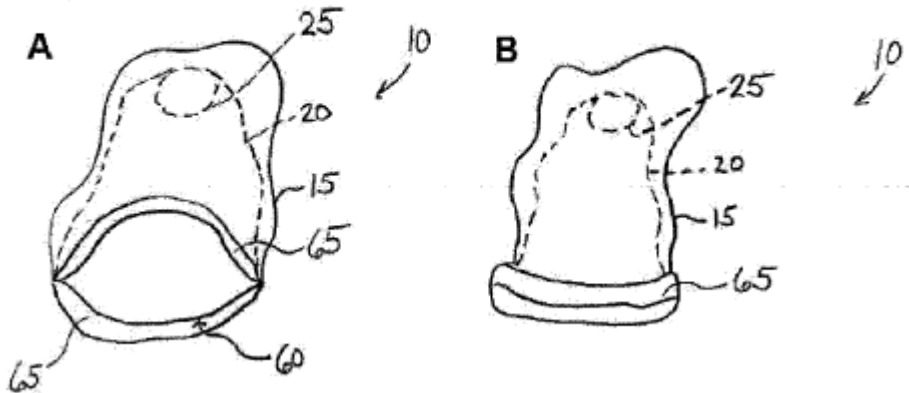
Asserted Claim 1 of the '213 Patent	Exemplary Citations to Zochowski
	<p>[0080] As shown in FIG. 6, the body 15 may be provided with a second aperture 60 capable of receiving the implant 30 for placement in the cavity 20. In a non-limiting example as best shown in FIG. 7A and FIG. 7B, the second aperture 60 may be provided with a closure 65 that may be selectively opened (FIG. 7A) and closed (FIG. 7B) for access to the cavity 20. The closure 65 may include, but is not limited to, a Zip-loc closure, a suture, zipper, button, adhesive, strings for tying for tying the second aperture 60 closed, and combinations thereof. The second aperture 60 may have a diameter less than, substantially equal to, or greater than the diameter of the implant 30.</p> <p>Zochowski, [0080].</p> <p style="text-align: center;"><b>FIGURE 6</b></p> 



Asserted Claim 1 of the '213 Patent	Exemplary Citations to Zochowski
	<p style="text-align: center;"><b>FIGURE 7</b></p>  <p>Zochowski, FIGS. 6-7.</p> <p><u>A person of ordinary skill in the art would observe that Zochowski further discloses that the body may be provided with a second aperture capable of receiving the implant for placement in the cavity. In one example implementation, second aperture 60 is at the opposite and proximal end of device 10 from first and distal aperture 25 used to pass the implant 30 (not shown in FIGS. 6-7) into the patient's tissue pocket.</u></p> <p><u>To the extent NovaPlast alleges that this limitation is not expressly or inherently disclosed in Zochowski, it would have been obvious in light of the knowledge of a person of ordinary skill in the art. A person of ordinary skill in the art would have been motivated to combine Zochowski with any of the other references identified in Defendants' Initial Invalidity Contentions regarding the '213 Patent below at least to the extent they desired to provide a flexible elongated member including a distal end formed opposite a closed proximal end and a longitudinal opening extending from the distal end, and which is closed using fasteners.</u></p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Zochowski
	<p><del>For example</del>More specifically, at least the references listed below disclose a flexible elongated member including a distal end formed opposite a closed proximal end and <u>having a longitudinal opening extending from the distal opening, and which is closed using fasteners.</u></p> <p>U.S. Pat. No. 9,168,126 to Preissman ("Preissman '126"), Exhibit <u>12</u> at 1.1.</p> <p>U.S. Pat. App. Pub. No. 2015/0032208 to Priessman ("Priessman '208"), Exhibit <u>34</u> at 1.1.</p> <p><del>U.S. Pat. No. 4,651,504 to Bentsen ("Bentsen"), Exhibit 6 at 1.1.</del></p> <p>U.S. Pat. No. 8,690,428 to Kruse ("Kruse"), Exhibit <u>58</u> at 1.1.</p> <p>U.S. Pat. No. 8,262,289 to Fratti ("Fratti"), Exhibit <u>69</u> at 1.1.</p> <p>U.S. Pat. App. Pub. No. 2007/0038310 to Guetty ("Guetty"), Exhibit <del>10</del><u>7</u> at 1.1.</p>
<p>[1.2] the distal end including a first longitudinal edge and a second longitudinal edge, the first longitudinal edge and second longitudinal edge further defining the longitudinal opening,</p>	<p>Zochowski discloses this limitation:</p> <p>[0080] As shown in FIG. 6, the body 15 may be provided with a second aperture 60 capable of receiving the implant 30 for placement in the cavity 20. In a non-limiting example as best shown in FIG. 7A and FIG. 7B, the second aperture 60 may be provided with a closure 65 that may be selectively opened (FIG. 7A) and closed (FIG. 7B) for access to the cavity 20. The closure 65 may include, but is not limited to, a Zip-loc closure, a suture, zipper, button, adhesive, strings for tying for tying the second aperture 60 closed, and combinations thereof. The second aperture 60 may have a diameter less than, substantially equal to, or greater than the diameter of the implant 30.</p> <p>Zochowski, [0080].</p>

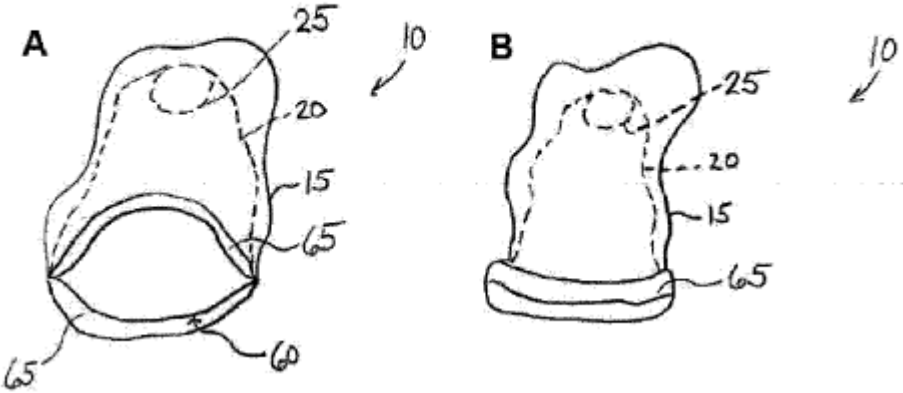
Asserted Claim 1 of the '213 Patent	Exemplary Citations to Zochowski
	<p style="text-align: center;"><b>FIGURE 7</b></p>  <p>Zochowski, FIG. 7.</p>
<p>[1.3] at least one first fastener formed on the elongated member adjacent the first longitudinal edge,</p> <p>and a second fastener formed on the elongated member adjacent the second longitudinal edge;</p> <p>[1.4] the second fastener adapted to matingly engage with the at least first fastener and to close the longitudinal opening,</p>	<p>Zochowski discloses this limitation:</p> <p>[0080] As shown in FIG. 6, the body 15 may be provided with a second aperture 60 capable of receiving the implant 30 for placement in the cavity 20. In a non-limiting example as best shown in FIG. 7A and FIG. 7B, the second aperture 60 may be provided with a closure 65 that may be selectively opened (FIG. 7A) and closed (FIG. 7B) for access to the cavity 20. The closure 65 may include, but is not limited to, a Zip-loc closure, a suture, zipper, button, adhesive, strings for tying for tying the second aperture 60 closed, and combinations thereof. The second aperture 60 may have a diameter less than, substantially equal to, or greater than the diameter of the implant 30.</p> <p>Zochowski, [0080].</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Zochowski
	<p style="text-align: center;"><b>FIGURE 7</b></p>  <p>Zochowski, FIG. 7.</p> <p><u>To the extent NovaPlast alleges that this limitation and the longitudinal opening limitation of [1.1] and [1.2] are not expressly or inherently disclosed in Zochowski, it would have been obvious in light of Guetty and the knowledge of a person of ordinary skill in the art.</u></p> <p><u>[0099] Sheath 5 is fitted with at least one lateral opening 6 arranged over all or part of its length. Said lateral opening 6 may extend, as shown in FIG. 1, essentially longitudinally over the length of sheath 5. It is altogether conceivable, without on this account leaving the framework of the invention, that this lateral opening 6 might extend in any other way, and for example transversally or helically. Said lateral opening 6 is closed by locking means 4 when case 2 is in the closed configuration (FIG. 1), said lateral opening 6 being opened up, in order to make possible the deformation of implant 1 into its functional configuration, when case 2 is in the open configuration (not shown).</u></p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Zochowski
	<p><u>Guetty, [0099].</u></p> <p><u>To the extent that Zochowski's disclosure of a second aperture, and an example embodiment with a Zip-loc closure for receiving an implant and closing the device to extrude the implant into the tissue pocket, one skilled in the art would be motivated to combine Zochowski according to Guetty to position the second aperture along a longitudinal axis of the device (i.e., perpendicular to the transverse orientation shown in Zochowski) and extending from the distal opening, because as disclosed in Guetty, such a longitudinal aperture and closure was one of a limited number of known configurations that could be successfully used for opening and closing devices for delivering implants out a distal end into a tissue pocket of a patient of the type described in Zochowski. Making such a change would have resulted in nothing more than the simple substitution of one known location and orientation for another, and there is a reasonable expectation that the use of a longitudinal orientation of a zip-loc closure system would be successful and would result in an enhanced and successful device because it was known in the art that such orientations were known from Guetty for use in implant delivery devices and would allow for a sterile and secured device for extruding an implant out the distal opening into the tissue pocket while preserving the sterile environment. Guetty, [0099]. Therefore, combining the teachings of Zochowski and Guetty is a simple substitution of a known element for another according to known methods that does no more than yield a predicable result, and also would be obvious to try given the limited number of alternative locations and orientations known to be suitable for an closeable aperture to be used for opening and closing an insertion device with a reasonable expectation of success, and in such case such a combination is obvious. For at least the foregoing reasons, such a modification would render obvious a distal opening defining the longitudinal opening as recited in [1.1]-[1.2].</u></p> <p><del>To the extent NovaPlast alleges that this limitation is not expressly or inherently disclosed in Zochowski, it would have been obvious in light of the knowledge of a person of ordinary skill in the art. A person of ordinary skill in the art would also have been motivated to combine Zochowski with any of the other references identified in Defendants' Initial Invalidity</del></p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Zochowski
	<p><del>Contentions regarding the '213 Patent</del> listed below at least to the extent they desired to provide a device with a distal end defining a longitudinal opening and the distal end including first and second longitudinal edges further defining the longitudinal opening <u>and fasteners that are formed on opposing sides of the longitudinal opening and that matingly engage to close the longitudinal opening.</u></p> <p><del>For example,</del> <u>More specifically,</u> at least the references listed below <u>also</u> disclose a flexible elongate member including a distal end and having a first longitudinal edge and a second longitudinal edge, the first longitudinal edge and second longitudinal edge further defining a longitudinal opening <u>and fasteners that are formed on opposing sides of the longitudinal opening and that matingly engage to close the longitudinal opening.</u></p> <p><del>U.S. Pat. No. 5,121,779 to Green ("Green"), Exhibit 1 at 1.2.</del>  U.S. Pat. No. 9,168,126 to Preissman ("Preissman '126"), Exhibit <del>21</del> at 1.2-1.4.  U.S. Pat. App. Pub. No. 2015/0032208 to Priessman ("Priessman '208"), Exhibit <del>43</del> at 1.2-1.4.  U.S. Pat. No. 5,078,189 to Ronsonet ("Ronsonet"), Exhibit <del>54</del> at 1.2-1.4.  <del>U.S. Pat. No. 4,651,504 to Bentsen ("Bentsen"), Exhibit 6 at 1.2.</del>  U.S. Pat. No. 8,690,428 to Kruse ("Kruse"), Exhibit <del>8-5</del> at 1.2, 1.3 and 1.4.  U.S. Pat. No. 8,262,289 to Fratti ("Fratti"), Exhibit <del>96</del> at 1.2, 1.3 and 1.4.  <del>U.S. Pat. App. Pub. No. 2007/0038310 to Guetty ("Guetty"), Exhibit 10 at 1.2.</del></p> <p><u>For example, Kruse and Fratti both disclose recloseable bag devices which are useable for containing and dispensing solid and/or liquid objects, including implants, and which have a distal end with a distal opening, a longitudinal opening extending therefrom, first and second longitudinal edges defining the longitudinal opening, and first and second fasteners that are formed on opposing sides of the longitudinal opening that matingly engage to close the longitudinal opening. See Exhibit 8 at 1.2-1.4 and Exhibit 9 at 1.2-1.4. One skilled in the art would be motivated to combine Zochowski according to Kruse or Fratti to position the second aperture beginning at the distal end opening and extending along a longitudinal axis of the device (i.e., perpendicular to the transverse orientation shown in Zochowski), because as disclosed in Kruse or Fratti, a second aperture extending longitudinally from a distal opening and closure comprising engaging fasteners adjacent to opposing edges of the longitudinal opening was one</u></p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Zochowski
	<p>of a limited number of known configurations that could be successfully used for opening an elongated flexible bag, inserting objects therein and closing the opening following insertion. Making such a change would have resulted in nothing more than the simple substitution of one known configuration of a second opening and closure, for another. Further, there is a reasonable expectation that the use of a longitudinal orientation of a zip-loc closure system, which extends from a distal end opening, would be successful and would result in an enhanced and successful device because it was known in the art that such configurations were known from Kruse and Fratti for use in recloseable bag-like devices, and it would have been obvious to one of ordinary skill in the art to look to the teachings of recloseable plastic bags, such as Kruse and Fratti, in developing a recloseable plastic bag-type device for containing and dispensing implants. Therefore, combining the teachings of Zochowski and Kruse or Fratti is a simple substitution of a known element for another according to known methods that does no more than yield a predictable result, and also would be obvious to try given the limited number of alternative locations and orientations known to be suitable for an aperture to be used for inserting objects into a bag-like device with a reasonable expectation of success, and in such case such a combination is obvious.</p>
<p>[1.5] whereby a predetermined size distal opening is formed based on the engagement of the second fastener with the at least one first fastener, the distal opening sized to allow the prosthetic implant to be urged therethrough.</p>	<p>Zochowski discloses this limitation:</p> <p><u>[0076]. It is to be understood that the implant 30 is insertable in the cavity 20 via the aperture 25. The aperture 25 may be smaller (or have a smaller diameter) than the implant 30, substantially same as the implant 30, or larger than the implant 30. In a non-limiting example as best shown in FIG. 15A and FIG. 15B, the aperture 25 may be smaller than the implant 30 and the body 15 may be resistant to stretching, thereby causing the implant 30 to extrude through the aperture 25.</u></p> <p><u>Zochowski, [0076].</u></p> <p>[0080] As shown in FIG. 6, the body 15 may be provided with a second aperture 60 capable of receiving the implant 30 for placement in the cavity 20. In a non-limiting example as best shown in FIG. 7A and FIG. 7B, the second aperture 60 may be provided with a closure 65 that may be selectively opened (FIG. 7A) and closed (FIG. 7B) for access to the cavity 20. The closure 65 may include, but is not limited to, a Zip-loc</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Zochowski
	<p data-bbox="730 274 1837 380">closure, a suture, zipper, button, adhesive, strings for tying for tying the second aperture 60 closed, and combinations thereof. The second aperture 60 may have a diameter less than, substantially equal to, or greater than the diameter of the implant 30.</p> <p data-bbox="678 412 930 444">Zochowski, [0080].</p> <p data-bbox="1094 518 1255 550"><b>FIGURE 7</b></p>  <p data-bbox="678 1053 930 1086">Zochowski, FIG. 7.</p> <p data-bbox="678 1110 1898 1175">The intended use of the device of claim 1, the type of object for insertion, and the size of the object are not material limitations.</p> <p data-bbox="678 1289 1898 1427">To the extent NovaPlast alleges that this limitation is not expressly or inherently disclosed in Zochowski, it would have been obvious in light of the knowledge of a person of ordinary skill in the art. A person of ordinary skill in the art would have been motivated to combine Zochowski with any of the other references identified in Defendants' Initial Invalidity Contentions</p>

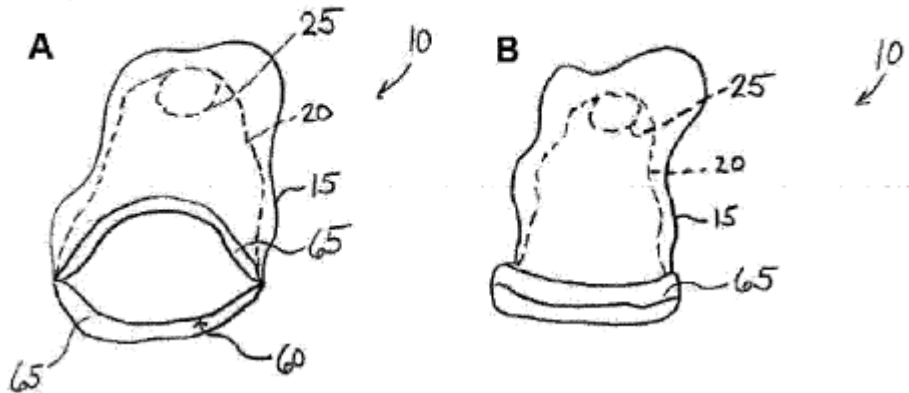


Asserted Claim 1 of the '213 Patent	Exemplary Citations to Zochowski
	<p>regarding the '213 Patent references listed below at least to the extent they desired to provide a device with a longitudinal opening that is closed by a first and second fastener, whereby engagement of the first and second fasteners forms a predetermined size distal opening that is sized to allow a prosthetic implant to be urged therethrough.</p> <p><del>For example</del> <u>More specifically</u>, at least the references listed below disclose a device with a longitudinal opening that is closed by a first and second fastener, whereby engagement of the first and second fasteners forms a predetermined size distal opening that is sized to allow <u>or is capable of allowing</u> a prosthetic implant to be urged therethrough.</p> <p>U.S. Pat. No. 5,121,779 to Green ("Green"), Exhibit 1 at 1.5.  U.S. Pat. No. 9,168,126 to Preissman ("Preissman '126"), Exhibit 2 at 1.5.  U.S. Pat. App. Pub. No. 2015/0032208 to Priessman ("Priessman '208"), Exhibit 43 at 1.5.  U.S. Pat. No. 5,078,189 to Ronsonet ("Ronsonet"), Exhibit 54 at 1.5.  U.S. Pat. No. 4,651,504 to Bentsen ("Bentsen"), Exhibit 6 at 1.5.  U.S. Pat. No. 4,825,915 to Hess ("Hess"), Exhibit 7 at 1.5.  U.S. Pat. No. 8,690,428 to Kruse ("Kruse"), Exhibit 85 at 1.5.  U.S. Pat. No. 8,262,289 to Fratti ("Fratti"), Exhibit 69 at 1.5.  U.S. Pat. App. Pub. No. 2007/0038310 to Guetty ("Guetty"), Exhibit 107 at 1.5.</p> <p><u>For example, Zowchowski discloses that the distal end aperture of its device may be smaller than the implant, substantially same as the implant, or larger than the implant and in each case is sized to allow the implant to be urged therethrough. See e.g., Zochowski [0076]. Thus, the modification of Zochowski in view of Guetty, Kruse, or Fratti discussed in connection with [1.2] to [1.4] would result in a structure in which engagement of the first fastener with the second fastener would necessarily form Zochowski's distal opening of a predetermined size, particularly, a size that allows an implant to be urged therethrough. Therefore, combining the teachings of Zochowski and any of Guetty, Kruse, Fratti is a simple substitution of a known element for another according to known methods that does no more than yield a predicable result. For at least the reasons noted below with respect to claim 5, combining Zochowski with Ronsonet would similarly obviate this limitation of claim 1. See discussion of Ronsonet in connection with claim 5, below.</u></p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Zochowski
	<p>The intended use of the device of claim 1, the type of object for insertion, and the size of the object are not material limitations.</p>

**CLAIM 5**

<b>Asserted Claim of the '213 Patent</b>	<b>Exemplary Citations to Zochowski</b>
<p>[5.0] 5. The delivery system of claim 1, each of the at least one first, fastener further comprising a channel, the second fastener defining a shoulder, the shoulder adapted to be received within and secured with the channel of at least one of the first fasteners.</p>	<p>Zochowski discloses the system of claim 1, <u>from which claim 5 depends for the reasons stated above. wherein Zochowski further discloses each of the at least one first, fasteners further each</u> comprising a channel, the second fastener defining a shoulder, the shoulder adapted to be received within and secured with the channel of at least one of the first fasteners.</p> <p>[0080] As shown in FIG. 6, the body 15 may be provided with a second aperture 60 capable of receiving the implant 30 for placement in the cavity 20. In a non-limiting example as best shown in FIG. 7A and FIG. 7B, the second aperture 60 may be provided with a closure 65 that may be selectively opened (FIG. 7A) and closed (FIG. 7B) for access to the cavity 20. The closure 65 may include, but is not limited to, a Zip-loc closure, a suture, zipper, button, adhesive, strings for tying for tying the second aperture 60 closed, and combinations thereof. The second aperture 60 may have a diameter less than, substantially equal to, or greater than the diameter of the implant 30.</p> <p>Zochowski, [0080].</p>

Asserted Claim of the '213 Patent	Exemplary Citations to Zochowski
	<p style="text-align: center;"><b>FIGURE 7</b></p>  <p>Zochowski, FIG. 7.</p> <p><u>To the extent NovaPlast alleges that Zochowski does not expressly or inherently disclose this limitation as construed by the Court to require a plurality of first fasteners each comprising a channel, it would have been obvious in light of the knowledge of a person of ordinary skill in the art. A person of ordinary skill in the art would have been motivated to combine Zochowski with any of the other references identified below at least to the extent they desired to provide a device with a longitudinal opening that is closed by a plurality of first fasteners comprising a channel and a second fastener comprising a shoulder.</u></p> <p><u>For example, at least the references listed below disclose a device with a longitudinal opening that is closed by a plurality of first fasteners and a second fastener, whereby engagement of the first and second fasteners forms a predetermined size distal opening that is sized to allow a prosthetic implant to be urged therethrough.</u></p>

Asserted Claim of the '213 Patent	Exemplary Citations to Zochowski
	<p><u>U.S. Pat. No. 5,078,189 to Ronsonet ("Ronsonet"), Exhibit 4 at 1.5.</u>  <u>U.S. Pat. No. 8,262,289 to Fratti ("Fratti"), Exhibit 6 at 5.0.</u>  <u>U.S. Pat. App. Pub. No. 2007/0038310 to Guetty ("Guetty"), Exhibit 7 at 1.5.</u></p> <p><u>More specifically, Ronsonet discloses the limitations of claim 5:</u></p> <p><u>What is provided is an apparatus which includes a rectangular sheet of flexible plastic, the first face of the sheet which includes a plurality of parallel spaced apart channels, and on the second face of the sheet including a pair of raised members, one raised member positioned substantially along a first edge of the sheet, and the second raised member positioned substantially perpendicular thereto along the bottom edge of the sheet, so that when the sheet is configured into a funnel shape, one of the raised locking members is mated into the channel members, to form a sealed juncture thereon, and for defining a sealed cone having an enlarged upper end and a reduced lower spout end, defining an overall funnel member.</u></p> <p><u>Ronsonet, 1:64-2:9</u></p> <p><u>With that locking concept in mind, reference is made now to FIGS. 3 and 4 of the apparatus, which illustrates the manner in which the apparatus is configured into a shape to function as an adjustable funnel apparatus 50 as illustrated in FIG. 4. It is quite commonplace that if one takes a substantially rectangular sheet as illustrated in FIGS. 1 and 2, that if one were to configure the positioning of the sheet as illustrated in FIG. 3, by rotating one face of the sheet in a circular fashion, that the sheet could be configured into a funnel apparatus as illustrated in FIG. 4. With that general concept in mind which is quite commonly known, reference is made to FIG. 3 where it is seen that the edge 18 of the apparatus has been formed into a circular pattern in the direction of arrow 40, and face 22 having the plurality of channel members 28 is being circulated around so that one of the parallel channel members 28 is brought into parallel locking alignment with horizontal raised locking member 38, and horizontal channel member</u></p>

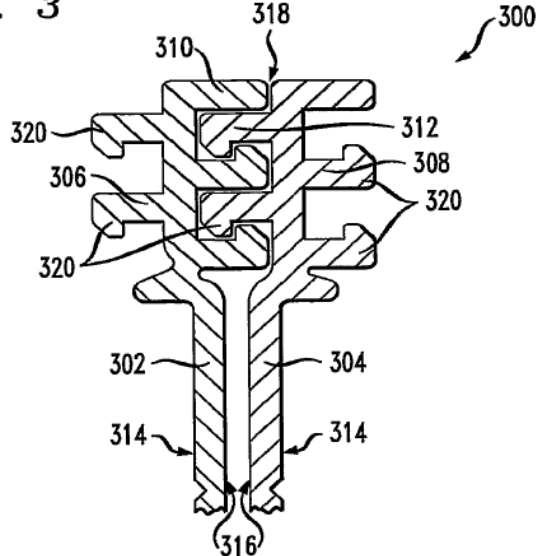
Asserted Claim of the '213 Patent	Exemplary Citations to Zochowski
	<p><u>34 is brought into parallel locking alignment with vertical raised locking member 36 along edge 20, as illustrated in phantom view in FIG. 4. Therefore, once the locking members have been pressed into locking relationship as with a ZIPLOCK® locking arrangement, FIG. 4 would define the funnel member 50 having an upper enlarged spout area 52, a continuous annular wall portion 54 which is then sealed along a common edge 56 via locking members 28, 38 and sealed along a top edge 58 via the locking relationship of locking members 34, 36. Further, as illustrated there would be further defined a reduced downspout opening 60 which is formed as a result of the manner in which the rectangular sheet 12 is placed into the configuration as illustrated.</u></p> <p><u>Turning now to the plurality of channel members 28 as they would configure into locking relationship with raised members 34, 36, as was discussed earlier, each of the channel members 28 are positioned in parallel relationship for defining a specific dimensional distance therebetween. Therefore, this dimensional distance as defined by the letter A in FIG. 3, results in a particular configuration of the diameter of downspout 60. There fore, as raised locking edge 38 is configured into locking engagement with a particular channel 28, the diameter of the downspout 60 formed thereby is of a dimension in direct relation to the change in the distance between the parallel channels 28. For example, if one were to assume that the diameter of downspout 60 in FIG. 4 is inch in the position that locking channel 28 locks with raised locking member 38, then were locking member 38 moved to the next channel 28B, as illustrated in FIG. 4, if that distance would be for example of an inch, then the diameter of the downspout 60 would be reduced of an inch. Therefore, with this relationship in mind, it is foreseen that the plurality of channels 28 allow one therefore to matingly engage a particular channel 28 with locking member 38, depending on the diameter of downspout 60 that one wishes to achieve in the final configuration of funnel member 50.</u></p> <p><u>Ronsonet, 3:51-4:41.</u></p>

Asserted Claim of the '213 Patent	Exemplary Citations to Zochowski
	<div data-bbox="682 284 1753 771"> </div> <p data-bbox="682 812 955 844"><u>Ronsonet, FIG. 3 – 4.</u></p> <p data-bbox="724 901 1837 1193"><u>It should be fully understood that this particular embodiment should not be limiting in the sense that the plurality of channel member 28 do not necessarily have to be evenly spaced apart, but could be configured into a particular dimensional arrangement i.e. one inch apart or even having a plurality of channel members along face 22 which would allow one to configure the funnel in a single funnel size, or in two or three or more funnel sizes depending on the location of the channel members 28. Therefore, it is foreseen that the sheets could be formed in many configurational sizes, and not limited to the sizes as illustrated in the Figures.</u></p> <p data-bbox="682 1209 924 1242"><u>Ronsonet, 4:42-53.</u></p> <p data-bbox="724 1299 1323 1331"><u>1. An adjustable funnel apparatus comprising:</u></p> <p data-bbox="724 1364 1743 1396"><u>a) a substantially flexible sheet member, having a first face and a second face;</u></p>

Asserted Claim of the '213 Patent	Exemplary Citations to Zochowski
	<p><u>b) at least one first channel running substantially along the width of said first face;</u></p> <p><u>c) a second channel running along a portion of the length of the first face and substantially perpendicular to the positioning of the at least one first channel;</u></p> <p><u>d) a first raised locking member running along adjacent an edge of the second face of the sheet member;</u></p> <p><u>e) a second raised locking member running along the lower edge of the second face and substantially perpendicular to the alignment of the first locking member;</u></p> <p><u>f) means for positioning the sheet member into a configuration so that one of the at least one first channel lockingly mates with the second raised locking member and the second channel mates with the first locking member, for defining a funnel shaped apparatus sealed by the locking engagement of one of the at least one first channel and the second channel to the second and first locking members respectively.</u></p> <p><u>Ronsonet, claim 1, 4:62-5:18.</u></p> <p><u>One skilled in the art would be motivated to modify Zochowski according to Ronsonet to utilize a plurality of first fasteners on one longitudinal edge of the elongated sleeve and a complementary second fastener on the opposing longitudinal edge of the elongate sleeve which one selected first fastener and second fastener can be matingly engaged for form a locked seal along the longitudinal edge and thereby define the size of the distal opening.</u></p> <p><u>Zochowski recognizes the problem of having to construct a sleeve configured to expel implants through an opening at a distal end of the sleeve into a tissue pocket, wherein at least the silicone implants vary in size and thus the dimension of the sleeve opening may vary. Zochowski, [0073], [0076], [0080].</u></p> <p><u>Ronsonet recognizes this same problem for funnels (i.e., a truncated, generally conical sleeve made of a flexible plastic material) that have to be provided with different sized distal end</u></p>



Asserted Claim of the '213 Patent	Exemplary Citations to Zochowski
	<p><u>openings according to the specific environment in which it will be used, and proposes an alternative solution that allows the user to select the size of the distal opening 60 through the implementation of a plurality of spaced apart raised members 36, 38 along one longitudinal edge of the sleeve, and a complementary fastener of channel members 28, 34 on the opposing longitudinal edge of the sleeve, wherein the selection of different ones of the raised members to mate with the opposing channel members along their entire length to form a “ziplocked” seal closing that longitudinal edge will result in different sized distal openings 60 according to the distances between the different ones of the plurality of raised channels 36, 38. (Ronsonet Col. 3, line 34 - Col. 4, line 41). Ronsonet also discloses that this solution has the advantage of providing a single product that can be sized by the user to have the desired sized distal opening for the environment of use and reduced size for storage when not in use. (Ronsonet Col. 1, lines 25-44).</u></p> <p><u>One skilled in the art would be motivated to make the substitution because an adjustable funnel having a longitudinal seal formed by the locking raised members and opposing channels would allow for improved scale and efficiency in manufacturing and reduced inventory in having a device with adjustable dimensions rather than stocking multiple different sized devices, and improved efficiency in use by allowing the user to select the size, and if the initial size was incorrect then the “ziplocked” seam could be unlocked and a different channel selected and the seam relocked at the correct size. One skilled in the art would understand that this substitution could be implemented successfully without impacting the need for preserving the sterile environment of the Zochowski device.</u></p> <p><u>Therefore, combining the teachings of Zochowski and Ronsonet is a combination of familiar elements according to known methods that does no more than yield a predicable result, and such a combination is obvious.</u></p> <p><u>By way of further example, Fratti discloses first fasteners comprising a plurality of channels on one side of a bag opening and one or more protrusions on the opposing side of the bag opening that are configured to matingly engage to close the opening. See e.g., Fratti, Exhibit 6, 5.0.</u></p>

Asserted Claim of the '213 Patent	Exemplary Citations to Zochowski
	<p><b>FIG. 3</b></p>  <p>Fratti, FIG. 3.</p> <p>Similarly, both Guetty and Zochowski disclose a closure mechanism for a second opening of an implant delivery device that can comprise a ziploc type of closure. See e.g., Guetty, Exhibit 7 at 5.0; Zochowski, [0080]. As would be known by a person of ordinary skill in the art, ziploc type closures can comprise one or more channels provided on one side of a bag opening and one or more complementary shaped structures (e.g., protrusions) provided on an opposing side of the opening that can be matingly engaged.</p>

## Exhibit 34

### U.S. Pat. No. 10,105,213 in view of U.S. App. Pub. No. 2015/0032208 to Priessman (“Priessman ‘208”)

As described in detail below, Priessman ‘208 anticipates and/or renders obvious claims 1 and 5 of U.S. Patent No. 10,105,213 to Weinzwieg (the “‘213 Patent” or “Patent-in-Suit”), which was filed on December 29, 2015 and issued on October 23, 2018, (collectively, the “Asserted Claims”) under 35 U.S.C. § 102 and/or § 103, either alone or in combination with U.S. Pat. No. 5,078,189 to Ronsonet (“Ronsonet”) or other prior art references, and/or in combination with the knowledge of a person of ordinary skill, as set forth in the following chart. Priessman ‘208 anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit as those claims have been applied by Plaintiff NovaPlast Corporation (“NovaPlast” or “Plaintiff”) in its Infringement Contentions and/or as construed by the Court in its [Markman] Opinion & Order dated July 26, 2023 (Dkt. 73) (the “Markman Order”)~~under Defendants’ understanding of the proper construction of the claims~~. To the extent it is found Priessman ‘208 or the additional references cited herein do ~~does~~ not expressly disclose certain limitations in the asserted claim, such limitations are inherent.

Priessman ‘208 was originally filed on Aug. 11, 2014 and published on Jan. 29, 2015, and is a continuation of application No. PCT/US12/24917 which published as WO2013122568 on Aug. 22, 2013, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Priessman ‘208. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Priessman ‘208 (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Priessman ‘208 and/or its prior art status, as evidence that the technology described in Priessman ‘208 anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Zochowski was originally filed on Jun. 19, 2012 and published on Aug. 14, 2014, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Zochowski. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Zochowski (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Zochowski and/or its prior art status, as evidence that the technology described in Zochowski anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Ronsonet was originally filed on Nov. 8, 1990 and issued on Jan. 7, 1992, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in

Ronsonet. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Ronsonet (including product samples, and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Ronsonet and/or its prior art status, as evidence that the technology described in Ronsonet renders obvious the Asserted Claims of the Patent-in-Suit.

Fratti was originally filed on Jan. 31, 2007 and issued on Sept. 11, 2012, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Fratti. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Fratti (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Fratti and/or its prior art status, as evidence that the technology described in Fratti anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Guetty was originally filed on Jul. 16, 2004 and published on Feb. 15, 2007, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Guetty. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Guetty (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Guetty and/or its prior art status, as evidence that the technology described in Guetty anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

The cited portions of Priessman ‘208, Zochowski, Fratti, Guetty and Ronsonet are merely illustrative, and Defendants reserve the right to rely on alternative or additional evidence, including uncited portions of Priessman ‘208, Fratti, Guetty and Ronsonet. Where the chart below states that Priessman ‘208, Zochowski, Fratti, Guetty or Ronsonet “describes,” “discloses,” or “provides for” a limitation, such disclosure may be express, inherent, or implicit. If not anticipated, one or more claims of the Patent-in-Suit are rendered obvious in light of Priessman ‘208 alone or Priessman ‘208 in combination with Zochowski, Fratti, Guetty, or Ronsonet or other prior art references and/or with the knowledge of a person of ordinary skill in the art.

This chart is subject to all reservations, objections, and disclaimers in Defendants’ Amended Initial Invalidity Contentions and any amendment, supplement, or modification thereof, which are incorporated herein by reference in their entirety. Nothing stated herein shall be treated as an admission or suggestion that Defendants agree with NovaPlast regarding either the scope of the Asserted Claims or the claim constructions advanced by NovaPlast in its Infringement Contentions or anywhere else, or that any of Defendants’ accused products meet any limitation of the Asserted Claims. ~~Nothing stated herein shall be construed as an admission or a waiver of any~~

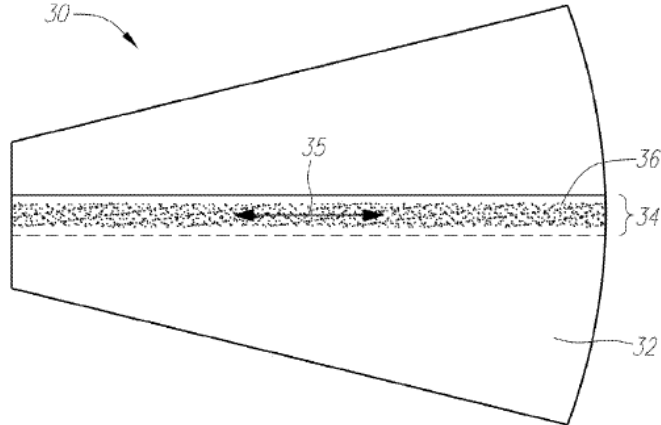
| ~~particular construction of any claim term.~~ Nothing stated herein shall be construed as an admission that the Asserted Claims are directed to patent-eligible subject matter. Defendants also reserve all rights to challenge any of the claim terms herein under 35 U.S.C. § 112, including by arguing that they are indefinite, not supported by the written description, and/or not enabled. Nothing stated herein shall be construed as an admission or waiver with respect to the effective filing date of the Asserted Claims.

**U.S. Pat. No. 10,105,213 in view of  
U.S. Pat. App. Pub. No. 2015/0032208 to Priessman (“Priessman ‘208”)**

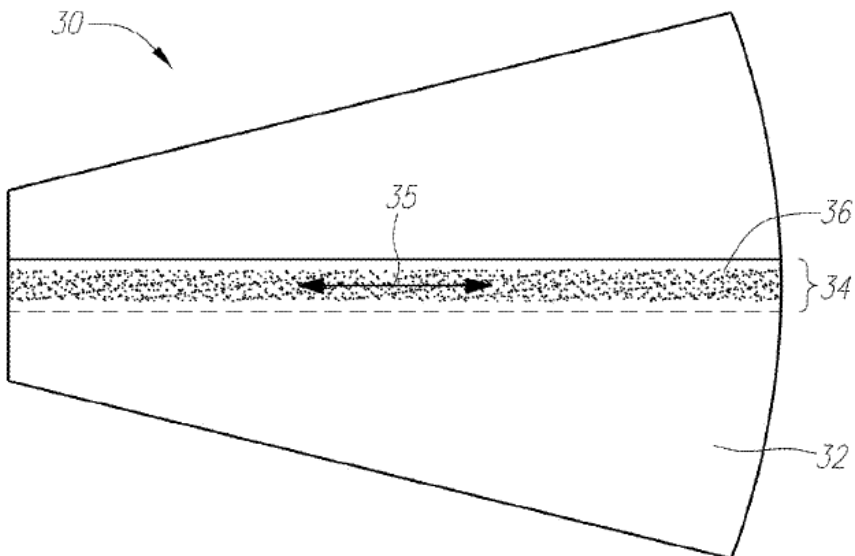
**CLAIM 1**

<b>Asserted Claim 1 of the ‘213 Patent</b>	<b>Exemplary Citations to Priessman ‘208</b>
<p>[1.p] 1. A delivery system adapted to facilitate insertion of a prosthetic implant through a surgical opening, the system comprising:</p>	<p>To the extent the preamble is limiting, Priessman ‘208 discloses this limitation:</p> <p style="padding-left: 40px;">A tapered sleeve (4) is provided for implant delivery (2). An implant (e.g., a pre-filled silicon breast implant) is introduced into a large proximal end of the sleeve and extruded into a surgical pocket of minimal access incision size through a small-sized distal end of the device. Features of the delivery system are provided to assist in sterile preparation, ensure one time use, improve the delivery of high-friction implants and/or achieve a combination of the above.</p> <p>Priessman ‘208, Abstract</p>
<p>[1.1] a flexible elongated member defining a proximal end and a distal end, the proximal end formed opposite the distal end and defining a closed end, the distal end defining a longitudinal opening;</p>	<p>Priessman ‘208 discloses this limitation:</p> <p style="padding-left: 40px;">[0007] A truncated, generally conical sleeve is described that can be, e.g., a frustum-shaped device. The device can have two ends and be adapted to receive an implant through a larger end (measured generally by width or peripheral dimension) and squeezed to expel the implant through the smaller end into a tissue pocket. The implant delivery sleeve can be constructed of a flexible material and can be similar in size to commercially available pastry bags.</p> <p>Priessman ‘208, [0007].</p> <p style="padding-left: 40px;">[0020] In yet another variation, the funnel is packaged and sold in a pre-hydrated configuration with both ends sealed containing the hydrating fluid and implant.</p> <p>Priessman ‘208, [0020].</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Priessman '208
	<div data-bbox="1113 259 1491 860" data-label="Image"> </div> <p data-bbox="1218 876 1365 917"><b>FIG. 1B</b></p> <p data-bbox="672 933 1008 966">Priessman '208, FIG. 1B.</p> <p data-bbox="735 1023 1848 1096">[0055] Tape or adhesive 11 may be used to similarly close and seal the proximal end 22 of the sleeve 4.</p> <p data-bbox="672 1112 987 1144">Priessman '208, [0055].</p> <p data-bbox="735 1201 1848 1274"><u>[0056] FIG. 2A is a construction view of another embodiment of sleeve 30. Here sleeve 4 comprises film 32 joined along a seam 34.</u></p> <p data-bbox="672 1291 987 1323"><u>Priessman '208, [0056].</u></p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Priessman '208
	 <p style="text-align: center;"><i>FIG. 2A</i></p> <p><u>Priessman '208, FIG. 2A.</u></p>
[1.2] the distal end including a first longitudinal edge and a second longitudinal edge, the first longitudinal edge and second longitudinal edge further defining the longitudinal opening,	Priessman '208 discloses this limitation:



Asserted Claim 1 of the '213 Patent	Exemplary Citations to Priessman '208
	 <p style="text-align: center;"><b>FIG. 2A</b></p> <p>Priessman '208, FIG. 2A.</p> <p>[0056] FIG. 2A is a construction view of another embodiment of sleeve 30. Here sleeve 4 comprises film 32 joined along a seam 34. <u>Seam 34 incorporates one more lengths of heat shrink material 36, oriented to contract along an axis as indicated by the double-arrow 35. ...</u></p> <p>[0057] <u>In assembly, the layered structure is set within a 'scissors' type heat sealer (using a thermal insulating batten within the funnel to protect both sides of the film from being welded together) to weld one or more pieces of heat shrink tubing along an overlapped or "lap" joint seam between length-wise ends of the film material from</u></p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Priessman '208
	<p><u>which the sleeve 4 is constructed.</u></p> <p>Priessman '208, [0056]-[0057].</p> <p><del>To the extent NovaPlast alleges that this limitation is not expressly or inherently disclosed in Priessman '208, it would have been obvious in light of the knowledge of a person of ordinary skill in the art. A person of ordinary skill in the art would have been motivated to combine Priessman '208 with any of the other references identified in Defendants' Initial Invalidity Contentions regarding the '213 Patent at least to the extent they desired to provide a device with a distal end defining a longitudinal opening and the distal end including first and second longitudinal edges further defining the longitudinal opening.</del></p> <p><del>For example, at least the references listed below disclose a flexible elongate member including a distal end and having a first longitudinal edge and a second longitudinal edge, the first longitudinal edge and second longitudinal edge further defining a longitudinal opening.—</del></p> <p><del>U.S. Pat. No. 5,121,779 to Green ("Green"), Exhibit 1 at 1.2.</del></p> <p><del>U.S. Pat. No. 9,168,126 to Preissman ("Preissman '126"), Exhibit 2 at 1.2.</del></p> <p><del>U.S. Pat. App. Pub. No. 2014/0228951 to Zochowski ("Zochowski"), Exhibit 3 at 1.2.</del></p> <p><del>U.S. Pat. No. 5,078,189 to Ronsonet ("Ronsonet"), Exhibit 5 at 1.2.</del></p> <p><del>U.S. Pat. No. 4,651,504 to Bentsen ("Bentsen"), Exhibit 6 at 1.2.</del></p> <p><del>U.S. Pat. No. 8,690,428 to Kruse ("Kruse"), Exhibit 8 at 1.2.</del></p> <p><del>U.S. Pat. No. 8,262,289 to Fratti ("Fratti"), Exhibit 9 at 1.2.</del></p> <p><del>U.S. Pat. App. Pub. No. 2007/0038310 to Guetty ("Guetty"), Exhibit 10 at 1.2.</del></p>
<p>[1.3] at least one first fastener formed on the elongated member adjacent the first longitudinal edge,</p> <p>and a second fastener formed on the elongated member adjacent the second longitudinal edge;</p>	<p>Priessman '208 discloses this limitation:</p> <p>[0056] FIG. 2A is a construction view of another embodiment of sleeve 30. Here sleeve 4 comprises film 32 joined along a seam 34. Seam 34 incorporates one or more lengths of heat shrink material 36, oriented to contract along an axis as indicated by the double-arrow 35. An example material is 70% shrink PET at 0.0028" thickness (as available from Dunstone, Inc.) cut in strips (or tape) made from rings of sleeve material.</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Priessman '208
<p>[1.4] the second fastener adapted to matingly engage with the at least first fastener and to close the longitudinal opening,</p>	<p>In other words, the strips are provided so as to shrink along longitudinal axis 35.</p> <p>[0057] In assembly, the layered structure is set within a “scissors” type heat sealer (using an thermal insulating batten within the funnel to protect both sides of the film from being welded together) to weld one or more pieces of heat shrink tubing along an overlapped or “lap” joint seam between length-wise ends of the film material from which the sleeve 4 is constructed. In this example, film 32 comprises 0.008” thick PVC (as available from Adam's Plastic of Chicago, Ill.).</p> <p>[0058] In any case, when constrained during heating, contraction of the heat shrink is prevented but the elements are bonded together. In another construction approach, heat shrink material can be sandwiched between opposing layers of double-sided tape.</p> <p>Priessman '208, [0056]-[0058].</p> <p>To the extent NovaPlast alleges that this limitation <u>and the longitudinal opening limitation of [1.1] and [1.2]</u> <del>is are</del> not expressly or inherently disclosed in Priessman '208, it would have been obvious in light of the knowledge of a person of ordinary skill in the art. A person of ordinary skill in the art would have been motivated to combine Priessman '208 with any of the other references identified in Defendants' Initial Invalidation Contentions regarding the '213 Patent <u>below</u> at least to the extent they desired to provide a device with an elongated member having a longitudinal opening including first and second fasteners formed on respective edges of the elongated member and adapted to matingly engage to close the longitudinal opening.</p> <p>For example, at least the references listed below disclose a flexible elongated member having a longitudinal opening including first and second fasteners formed on respective edges of the elongated member and adapted to matingly engage to close the opening.</p> <p><del>U.S. Pat. No. 5,121,779 to Green (“Green”), Exhibit 1 at 1.3-1.4.</del></p> <p><del>U.S. Pat. No. 9,168,126 to Preissman (“Preissman '126”), Exhibit 2 at 1.3-1.4.</del></p> <p><del>U.S. Pat. App. Pub. No. 2014/0228951 to Zochowski (“Zochowski”), Exhibit 3 at 1.3-1.4.</del></p> <p><del>U.S. Pat. No. 5,078,189 to Ronsonet (“Ronsonet”), Exhibit 5 at 1.3-1.4.</del></p> <p><del>U.S. Pat. No. 4,651,504 to Bentsen (“Bentsen”), Exhibit 6 at 1.3-1.4.</del></p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Priessman '208
	<p>U.S. Pat. No. 8,690,428 to Kruse ("Kruse"), Exhibit 8 at 1.3-1.4.  U.S. Pat. No. 8,262,289 to Fratti ("Fratti"), Exhibit 9 at 1.3-1.4.  U.S. Pat. App. Pub. No. 2007/0038310 to Guetty ("Guetty"), Exhibit 10 at 1.3-1.4.</p> <p><u>For example, to the extent NovaPlast alleges that this limitation and the longitudinal opening limitation of [1.1] and [1.2] are not expressly or inherently disclosed in Priessman '208, it would have been obvious in light of Guetty and the knowledge of a person of ordinary skill in the art.</u></p> <p><u>[0099] Sheath 5 is fitted with at least one lateral opening 6 arranged over all or part of its length. Said lateral opening 6 may extend, as shown in FIG. 1, essentially longitudinally over the length of sheath 5. It is altogether conceivable, without on this account leaving the framework of the invention, that this lateral opening 6 might extend in any other way, and for example transversally or helically. Said lateral opening 6 is closed by locking means 4 when case 2 is in the closed configuration (FIG. 1), said lateral opening 6 being opened up, in order to make possible the deformation of implant 1 into its functional configuration, when case 2 is in the open configuration (not shown).</u></p> <p><u>Guetty, [0099].</u></p> <p><u>According to another alternative exemplary embodiment, locking means 4 can be formed from a "Ziplock®" zipper system, said zipper making possible the opening or closing of case 2, and being to this end linked to a traction thread forming opener member 3.</u></p> <p><u>Guetty [0146]</u></p> <p><u>To the extent that Priessman '208's disclosure of a longitudinal opening that is closed using, for example, heat shrink material can be sandwiched between opposing layers of double-sided tape, for closing the device to extrude the implant into the tissue pocket, one skilled</u></p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Priessman '208
	<p><u>in the art would be motivated to combine Priessman '208 according to Guetty so as to utilize opposed mating structures such as a zip-loc fastener to join the opposing edges of Priessman '208's film, because as disclosed in Guetty, such a longitudinal aperture and closure was one of a limited number of known configurations that could be successfully used for opening or closing devices for delivering implants into a tissue pocket of a patient of the type described in Priessman '208. Making such a change would have resulted in nothing more than the simple substitution of one known type of fastener construction (e.g., two opposing layers of double-sided adhesive tape) for another (e.g., two opposing, complementary zip-loc structures) and there is a reasonable expectation that the use of a zip-loc closure system would be successful and would result in an enhanced and successful device because it was known in the art that such fasteners were known from Guetty for use in implant delivery devices and would allow for a sterile and secured device for delivery an implant out of the distal opening into the tissue pocket while preserving the sterile environment. Guetty, [0099]. Therefore, combining the teachings of Priessman '208 and Guetty is a simple substitution of a known element for another according to known methods that does no more than yield a predicable result, and also would be obvious to try given the limited number of fasteners known to be suitable for closing a longitudinal aperture of an implant delivery device with a reasonable expectation of success, and in such case such a combination is obvious. For at least the foregoing reasons, such a modification would render obvious a distal opening defining the longitudinal opening as recited in [1.1]-[1.2].</u></p>
<p>[1.5] whereby a predetermined size distal opening is formed based on the engagement of the second fastener with the at least one first fastener, the distal opening sized to allow the prosthetic implant to be urged therethrough.</p>	<p>Priessman '208 discloses this limitation:</p> <p>[0008] More specifically, since the size of silicone implants may vary in a range from about 150 cc to about 800 cc, the dimensions of the sleeve may vary. A proximal opening sized to fit any implant in this size range and a distal opening sized to fit the smallest implant may be desirable. The distal opening (or tip) may be enlargeable by trimming the sleeve. In fact, the device can be manufactured and sold without a distal opening, with the expectation that the user will trim the sleeve to create the</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Priessman '208
	<p>appropriately sized distal opening. Indicia may be present on the exterior of sleeve as a guide for cutting to the proper dimensions. Otherwise, a template or other means may be provided to assist in trimming.</p> <p>Priessman '208, [0008].</p> <p><u>[0019] It is also contemplated that the sleeve may be pretrimmed to correlate with the specific implant type and surface configuration. Alternatively, if pre-sealed, the exact location for optimum sizing of the distal end opening could be clearly marked with an indication (e.g., pad printing, silk screening, etc.) where to trim.</u></p> <p><u>Priessman '208, [0019].</u></p> <p><u>To the extent NovaPlast alleges that this limitation is not expressly or inherently disclosed in Priessman '208, it would have been obvious in light of the knowledge of a person of ordinary skill in the art. A person of ordinary skill in the art would have been motivated to combine Priessman '208 with any of the other references identified below at least to the extent they desired to provide a device with a longitudinal opening that is closed by a first and second fastener, whereby engagement of the first and second fasteners forms a predetermined size distal opening that is sized to allow a prosthetic implant to be urged therethrough.</u></p> <p><u>More specifically, at least the references listed below disclose a device with a longitudinal opening that is closed by a first and second fastener, whereby engagement of the first and second fasteners forms a predetermined size distal opening that is sized to allow or is capable of allowing a prosthetic implant to be urged therethrough.</u></p> <p><u>U.S. Pat. No. 5,078,189 to Ronsonet ("Ronsonet"), Exhibit 5 at 1.5.</u></p> <p><u>U.S. Pat. No. 8,262,289 to Fratti ("Fratti"), Exhibit 9 at 1.5.</u></p> <p><u>U.S. Pat. App. Pub. No. 2007/0038310 to Guetty ("Guetty"), Exhibit 10 at 1.5.</u></p> <p><u>For example, Priessman '208 discloses that the distal end aperture of its device may be sized to</u></p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Priessman '208
	<p>allow the implant to be urged therethrough. See e.g., Priessman '208 [0008]. Thus, the modification of Priessman '208 in view of Guetty, which as discussed above with respect to [1.2]-[1.4] discloses a longitudinal opening that can be opened or closed using, e.g., a zip-loc type of opposing fasteners, would result in a structure in which engagement of the first fastener with the second fastener to close the longitudinal opening would necessarily form a distal opening of a predetermined size, particularly, a size that allows an implant to be urged therethrough. Therefore, combining the teachings of Priessman '208 and Guetty is a simple substitution of a known element for another according to known methods that does no more than yield a predicable result. For at least the reasons noted below with respect to claim 5, combining Priessman '208 with Ronsonet would similarly obviate this limitation of claim 1. See discussion of Ronsonet in connection with claim 5, below.</p> <p>The intended use of the device of claim 1, the type of object for insertion, and the size of the object are not material limitations.</p>

**CLAIM 5**

<b>Asserted Claim of the '213 Patent</b>	<b>Exemplary Citations to Priessman '208</b>
<p>[5.0] 5. The delivery system of claim 1, each of the at least one first, fastener further comprising a channel, the second fastener defining a shoulder, the shoulder adapted to be received within and secured with the channel of at least one of the first fasteners.</p>	<p><u>This limitation is met.</u>  Priessman '208 discloses the system of claim 1, <u>from which this claim 5 depends, for the reasons stated above.</u></p> <p><u>Ronsonet discloses the limitations of claim 5:</u></p> <p><u>What is provided is an apparatus which includes a rectangular sheet of flexible plastic, the first face of the sheet which includes a plurality of parallel spaced apart channels, and on the second face of the sheet including a pair of raised members, one raised member positioned substantially along a first edge of the sheet, and the second raised member positioned substantially perpendicular thereto along the bottom edge of the sheet, so that when the sheet is configured into a funnel shape, one of the raised locking members is mated into the channel members, to form a sealed juncture thereon, and for defining a sealed cone having an enlarged upper end and a reduced lower spout end, defining an overall funnel member.</u></p> <p><u>Ronsonet, 1:64-2:9</u></p> <p><u>With that locking concept in mind, reference is made now to FIGS. 3 and 4 of the apparatus, which illustrates the manner in which the apparatus is configured into a shape to function as an adjustable funnel apparatus 50 as illustrated in FIG. 4. It is quite commonplace that if one takes a substantially rectangular sheet as illustrated in FIGS. 1 and 2, that if one were to configure the positioning of the sheet as illustrated in FIG. 3, by rotating one face of the sheet in a circular fashion, that the sheet could be configured into a funnel apparatus as illustrated in FIG. 4. With that general concept in mind which is quite commonly known, reference is made to FIG. 3 where it is seen that the edge 18 of the apparatus has been formed into a circular pattern in the direction of arrow 40, and face 22 having the plurality of channel members 28 is being circulated around so that one of the parallel channel members 28 is brought into parallel locking</u></p>



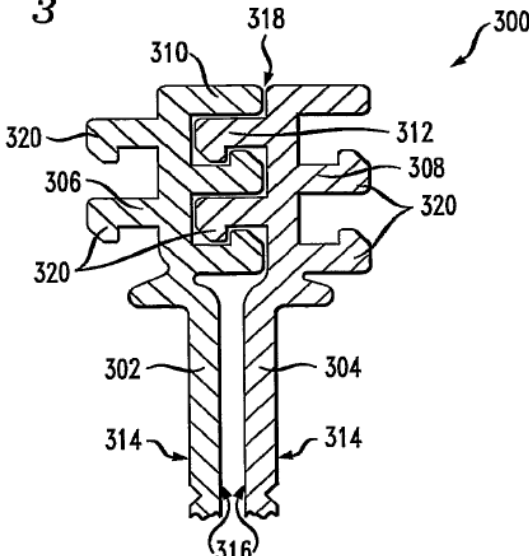
Asserted Claim of the '213 Patent	Exemplary Citations to Priessman '208
	<p><u>alignment with horizontal raised locking member 38, and horizontal channel member 34 is brought into parallel locking alignment with vertical raised locking member 36 along edge 20, as illustrated in phantom view in FIG. 4. Therefore, once the locking members have been pressed into locking relationship as with a ZIPLOCK® locking arrangement, FIG. 4 would define the funnel member 50 having an upper enlarged spout area 52, a continuous annular wall portion 54 which is then sealed along a common edge 56 via locking members 28, 38 and sealed along a top edge 58 via the locking relationship of locking members 34, 36. Further, as illustrated there would be further defined a reduced downspout opening 60 which is formed as a result of the manner in which the rectangular sheet 12 is placed into the configuration as illustrated.</u></p> <p><u>Turning now to the plurality of channel members 28 as they would configure into locking relationship with raised members 34, 36, as was discussed earlier, each of the channel members 28 are positioned in parallel relationship for defining a specific dimensional distance therebetween. Therefore, this dimensional distance as defined by the letter A in FIG. 3, results in a particular configuration of the diameter of downspout 60. There fore, as raised locking edge 38 is configured into locking engagement with a particular channel 28, the diameter of the downspout 60 formed thereby is of a dimension in direct relation to the change in the distance between the parallel channels 28. For example, if one were to assume that the diameter of downspout 60 in FIG. 4 is inch in the position that locking channel 28 locks with raised locking member 38, then were locking member 38 moved to the next channel 28B, as illustrated in FIG. 4, if that distance would be for example of an inch, then the diameter of the downspout 60 would be reduced of an inch. Therefore, with this relationship in mind, it is foreseen that the plurality of channels 28 allow one therefore to matingly engage a particular channel 28 with locking member 38, depending on the diameter of downspout 60 that one wishes to achieve in the final configuration of funnel member 50.</u></p> <p><u>Ronsonet, 3:51-4:41.</u></p>

Asserted Claim of the '213 Patent	Exemplary Citations to Priessman '208
	<div data-bbox="682 289 1753 771"> </div> <p data-bbox="682 812 955 844"><u>Ronsonet, FIG. 3 – 4.</u></p> <p data-bbox="724 901 1837 1193"><u>It should be fully understood that this particular embodiment should not be limiting in the sense that the plurality of channel member 28 do not necessarily have to be evenly spaced apart, but could be configured into a particular dimensional arrangement i.e. one inch apart or even having a plurality of channel members along face 22 which would allow one to configure the funnel in a single funnel size, or in two or three or more funnel sizes depending on the location of the channel members 28. Therefore, it is foreseen that the sheets could be formed in many configurational sizes, and not limited to the sizes as illustrated in the Figures.</u></p> <p data-bbox="682 1209 924 1242"><u>Ronsonet, 4:42-53.</u></p> <p data-bbox="724 1299 1323 1331"><u>1. An adjustable funnel apparatus comprising:</u></p> <p data-bbox="724 1364 1743 1396"><u>a) a substantially flexible sheet member, having a first face and a second face;</u></p>

Asserted Claim of the '213 Patent	Exemplary Citations to Priessman '208
	<p><u>b) at least one first channel running substantially along the width of said first face;</u></p> <p><u>c) a second channel running along a portion of the length of the first face and substantially perpendicular to the positioning of the at least one first channel;</u></p> <p><u>d) a first raised locking member running along adjacent an edge of the second face of the sheet member;</u></p> <p><u>e) a second raised locking member running along the lower edge of the second face and substantially perpendicular to the alignment of the first locking member;</u></p> <p><u>f) means for positioning the sheet member into a configuration so that one of the at least one first channel lockingly mates with the second raised locking member and the second channel mates with the first locking member, for defining a funnel shaped apparatus sealed by the locking engagement of one of the at least one first channel and the second channel to the second and first locking members respectively.</u></p> <p><u>Ronsonet, claim 1, 4:62-5:18.</u></p> <p><u>One skilled in the art would be motivated to modify Preissman '208 according to Ronsonet to utilize a plurality of first fasteners on one longitudinal edge of the elongated sleeve and a complementary second fastener on the opposing longitudinal edge of the elongate sleeve which one selected first fastener and second fastener can be matingly engaged for form a locked seal along the longitudinal edge and thereby define the size of the distal opening.</u></p> <p><u>Priessman '208 recognizes the problem of having to construct a truncated, generally conical sleeve to be squeezed to expel pre-filled, solid, and/or semi-solid implants through the smaller distal end into a tissue pocket, wherein at least the silicone implants vary in range from 150 cc to about 800 cc and the dimension of the sleeve may vary. Priessman '208, [0007]-[0008].</u></p> <p><u>Ronsonet recognizes this same problem for funnels (i.e., a truncated, generally conical sleeve made of a flexible plastic material) that have to be provided with different sized distal end</u></p>

Asserted Claim of the '213 Patent	Exemplary Citations to Priessman '208
	<p><u>openings according to the specific environment in which it will be used, and proposes an alternative solution that allows the user to select the size of the distal opening 60 through the implementation of a plurality of spaced apart raised members 36, 38 along one longitudinal edge of the sleeve, and a complementary fastener of channel members 28, 34 on the opposing longitudinal edge of the sleeve, wherein the selection of different ones of the raised members to mate with the opposing channel members along their entire length to form a “ziplocked” seal closing that longitudinal edge will result in different sized distal openings 60 according to the distances between the different ones of the plurality of raised channels 36, 38. (Ronsonet Col. 3, line 34 - Col. 4, line 41). Ronsonet also discloses that this solution has the advantage of providing a single product that can be sized by the user to have the desired sized distal opening for the environment of use and reduced size for storage when not in use. (Ronsonet Col. 1, lines 25-44).</u></p> <p><u>One skilled in the art would be motivated to make the substitution because an adjustable funnel having a longitudinal seal formed by the locking raised members and opposing channels would allow for improved scale and efficiency in manufacturing and reduced inventory in having a device with adjustable dimensions rather than stocking multiple different sized devices, and improved efficiency in use by allowing the user to select the size, and if the initial size was incorrect then the “ziplocked” seam could be unlocked and a different channel selected and the seam relocked at the correct size, whereas in the Priessman '208 disclosure the sleeve having too large a distal opening or a distal opening not cut cleanly would have to be discarded and a new sleeve, and there is a reasonable expectation that the substitution would be successful and would result in a sleeve having adjustable dimensions to established the proper sized distal opening for the implant to be delivered therethrough into the tissue pocket. One skilled in the art would understand that this substitution could be implemented successfully without impacting the need for preserving the sterile environment of the Priessman '208 device.</u></p> <p><u>Therefore, combining the teachings of Preissman '208 and Ronsonet is a combination of familiar elements according to known methods that does no more than yield a predicable result, and such a combination is obvious.</u></p>

Asserted Claim of the '213 Patent	Exemplary Citations to Priessman '208
	<p><del>wherein each of the at least one first, fastener further comprising a channel, the second fastener defining a shoulder, the shoulder adapted to be received within and secured with the channel of at least one of the first fasteners.</del></p> <p><del>To the extent NovaPlast alleges that this limitation is not expressly or inherently disclosed in Priessman '208, it would have been obvious in light of the knowledge of a person of ordinary skill in the art. Furthermore, A a person of ordinary skill in the art would have been motivated to combine Priessman '208 with any of the other references identified in Defendants' Initial Invalidity Contentions regarding the '213 Patent below at least to the extent they desired using a plurality of first fasteners comprising a channel and a fastener comprising a shoulder that is received and secured within the a channel.</del></p> <p>For example, at least the references listed below disclose a device with an opening that is closed by <u>fasteners a first fastener comprising a plurality of channels</u> and a second fastener comprising a shoulder, the shoulder adapted to be received within and secured with the channel of the first fastener.</p> <p><del>U.S. Pat. No. 5,121,779 to Green ("Green"), Exhibit 1 at 5.0.</del>  <del>U.S. Pat. App. Pub. No. 2014/0228951 to Zochowski ("Zochowski"), Exhibit 23 at 5.0.</del>  <del>U.S. Pat. No. 5,078,189 to Ronsonet ("Ronsonet"), Exhibit 5 at 5.0.</del>  <del>U.S. Pat. No. 4,651,504 to Bentsen ("Bentsen"), Exhibit 6 at 5.0.</del>  <del>U.S. Pat. No. 8,690,428 to Kruse ("Kruse"), Exhibit 8 at 5.0.</del>  <del>U.S. Pat. No. 8,262,289 to Fratti ("Fratti"), Exhibit 97 at 5.0.</del>  <del>U.S. Pat. App. Pub. No. 2007/0038310 to Guetty ("Guetty"), Exhibit 107 at 5.0.</del></p> <p><u>For example, Fratti discloses first fasteners comprising a plurality of channels on one side of a bag opening and one or more protrusions on the opposing side of the bag opening that are configured to matingly engage to close the opening. See e.g., Fratti, Exhibit 6, 5.0.</u></p>

Asserted Claim of the '213 Patent	Exemplary Citations to Priessman '208
	<p><b>FIG. 3</b></p>  <p>Fratti, FIG. 3.</p> <p>Similarly, both Guetty and Zochowski disclose a closure mechanism for a second opening of an implant delivery device that can comprise a ziploc type of closure. See e.g., Guetty, Exhibit 7 at 5.0; Zochowski, Exhibit 2 at 5.0. As would be known by a person of ordinary skill in the art, ziploc type closures can comprise one or more channels provided on one side of a bag opening and one or more complementary shaped structures (e.g., protrusions) provided on an opposing side of the opening that can be matingly engaged.</p>

## Exhibit ~~45~~

### U.S. Pat. No. 10,105,213 in view of U.S. Pat. No. 5,078,189 to Ronsonet (“Ronsonet”)

As described in detail below, Ronsonet anticipates and/or renders obvious claims 1 and 5 of U.S. Patent No. 10,105,213 to Weinzweig (the “’213 Patent” or “Patent-in-Suit”), which was filed on December 29, 2015 and issued on October 23, 2018, (collectively, the “Asserted Claims”) under 35 U.S.C. § 102 and/or § 103, either alone or in combination with other prior art references, and/or in combination with the knowledge of a person of ordinary skill, as set forth in the following chart. Ronsonet anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit as those claims have been applied by Plaintiff NovaPlast Corporation (“NovaPlast” or “Plaintiff”) in its Infringement Contentions and/or as construed by the Court in its [Markman] Opinion & Order dated July 26, 2023 (Dkt. 73) (the “Markman Order”)~~under Defendants’ understanding of the proper construction of the claims~~. To the extent it is found Ronsonet or the additional references cited herein does not expressly disclose certain limitations in the asserted claim, such limitations are inherent.

Ronsonet was originally filed on Nov. 8, 1990 and issued on Jan. 7, 1992, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Ronsonet. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Ronsonet (including product samples, and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Ronsonet and/or its prior art status, as evidence that the technology described in Ronsonet anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Preissman ‘126 was originally filed on Mar. 27, 2012, published as App. Pub. No. 2012/0185042 on Jul. 19, 2012, and issued on Oct. 27, 2015, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Preissman ‘126. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Preissman ‘126 (including product samples, and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Preissman ‘126 and/or its prior art status, as evidence that the technology described in Preissman ‘126 anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Zochowski was originally filed on Jun. 19, 2012 and published on Aug. 14, 2014, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Zochowski. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the

technology described in Zochowski (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Zochowski and/or its prior art status, as evidence that the technology described in Zochowski anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Priessman '208 was originally filed on Aug. 11, 2014 and published on Jan. 29, 2015, and is a continuation of application No. PCT/US12/24917 which published as WO2013122568 on Aug. 22, 2013, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Priessman '208. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Priessman '208 (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Priessman '208 and/or its prior art status, as evidence that the technology described in Priessman '208 anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Kruse was originally filed on Nov. 12, 2009 and issued on Apr. 8, 2014, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Kruse. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Kruse (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Kruse and/or its prior art status, as evidence that the technology described in Kruse anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Fratti was originally filed on Jan. 31, 2007 and issued on Sept. 11, 2012, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Fratti. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Fratti (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Fratti and/or its prior art status, as evidence that the technology described in Fratti anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Guetty was originally filed on Jul. 16, 2004 and published on Feb. 15, 2007, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Guetty. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Guetty (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Guetty and/or its prior



art status, as evidence that the technology described in Guetty anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

The cited portions of Ronsonet, Priessman '126, Zochowski, Priessman '208, Kruse, Fratti and Guetty are merely illustrative, and Defendants reserve the right to rely on alternative or additional evidence, including uncited portions of Ronsonet, Priessman '126, Zochowski, Priessman '208, Kruse, Fratti or Guetty. Where the chart below states that Ronsonet, Priessman '126, Zochowski, Priessman '208, Kruse, Fratti or Guetty “describes,” “discloses,” or “provides for” a limitation, such disclosure may be express, inherent, or implicit. If not anticipated, one or more claims of the Patent-in-Suit are rendered obvious in light of Ronsonet alone or Ronsonet in combination with Priessman '126, Zochowski, Priessman '208, Kruse, Fratti or Guetty or other prior art references and/or with the knowledge of a person of ordinary skill in the art.

This chart is subject to all reservations, objections, and disclaimers in Defendants’ ~~Initial~~ Amended Invalidity Contentions and any amendment, supplement, or modification thereof, which are incorporated herein by reference in their entirety. Nothing stated herein shall be treated as an admission or suggestion that Defendants agree with NovaPlast regarding either the scope of the Asserted Claims or the claim constructions advanced by NovaPlast in its Infringement Contentions or anywhere else, or that any of Defendants’ accused products meet any limitation of the Asserted Claims. ~~Nothing stated herein shall be construed as an admission or a waiver of any particular construction of any claim term.~~ Nothing stated herein shall be construed as an admission that the Asserted Claims are directed to patent-eligible subject matter. Defendants also reserve all rights to challenge any of the claim terms herein under 35 U.S.C. § 112, including by arguing that they are indefinite, not supported by the written description, and/or not enabled. Nothing stated herein shall be construed as an admission or waiver with respect to the effective filing date of the Asserted Claims.

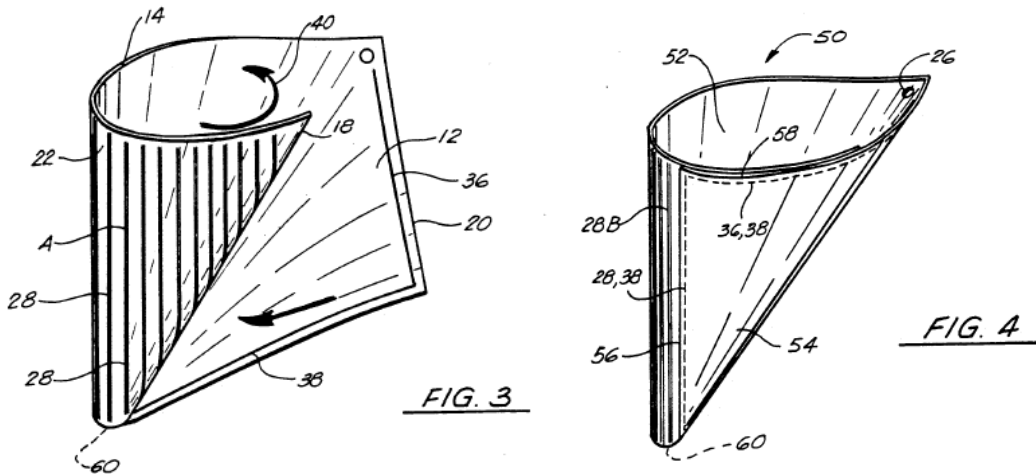
**U.S. Pat. No. 10,105,213 in view of  
U.S. Pat. No. 5,078,189 to Ronsonet (“Ronsonet”)**

**CLAIM 1**

<b>Asserted Claim 1 of the ‘213 Patent</b>	<b>Exemplary Citations to Ronsonet</b>
<p>[1.p] 1. A delivery system adapted to facilitate insertion of a prosthetic implant through a surgical opening, the system comprising:</p>	<p>To the extent the preamble is limiting, Ronsonet discloses this limitation:</p> <p style="padding-left: 40px;">The present invention relates to funnels. More particularly, the present invention relates to an adjustable funnel apparatus which includes a flat elongated wall portion shapable into a cone, and sealed along a common edge for defining a funnel having varied size flow ports depending on the sealing portion utilized.</p> <p>Ronsonet, 1:5-11.</p> <p style="padding-left: 40px;">In the present concept of funnels, there are two basic problems encountered in a use of every day funnels. One problem addresses the relative size of the funnel vis-a-vis the size of the pour spout. Because of the nature of a funnel and the many uses that a funnel can be put to, it is required that funnels come in various sizes so that various types of uses can be easily accommodated depending on the port that the fluid is being poured into.</p> <p>Ronsonet, 1:25-33.</p>
<p>[1.1] a flexible elongated member defining a proximal end and a distal end, the proximal end formed opposite the distal end and defining a closed end, the distal end defining a longitudinal opening;</p>	<p>Ronsonet discloses this limitation:</p> <p style="padding-left: 40px;">FIGS. 1-4 illustrate the preferred embodiment of the apparatus of the present invention by the numeral 10. As illustrated, apparatus 10 would comprise generally a flat rectangular sheet member 12 which would be constructed of a flexible material such as plastic or the like of a thickness so that the member could be easily configured into a cone shape as will be discussed further.</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Ronsonet
	<p data-bbox="682 272 924 305">Ronsonet, 2:35-62.</p> <div data-bbox="682 357 1722 836"> </div> <p data-bbox="682 876 955 909">Ronsonet, FIG. 3 – 4.</p> <p data-bbox="735 966 1837 1258">Therefore, once the locking members have been pressed into locking relationship as with a ZIPLOCK® locking arrangement, FIG. 4 would define the funnel member 50 having an upper enlarged spout area 52, a continuous annular wall portion 54 which is then sealed along a common edge 56 via locking members 28, 38 and sealed along a top edge 58 via the locking relationship of locking members 34, 36. Further, as illustrated there would be further defined a reduced downspout opening 60 which is formed as a result of the manner in which the rectangular sheet 12 is placed into the configuration as illustrated.</p> <p data-bbox="682 1274 913 1307">Ronsonet, 4:4-16.</p> <p data-bbox="682 1347 1890 1412">To the extent NovaPlast alleges that this limitation is not expressly or inherently disclosed in Ronsonet, it would have been obvious in light of the knowledge of a person of ordinary skill in</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Ronsonet
	<p>the art. A person of ordinary skill in the art would have been motivated to combine Ronsonet with any of the other references identified in <del>Defendants' Initial Invalidity Contentions regarding the '213 Patent</del><u>below</u> at least to the extent they desired to provide a flexible elongated member including a distal end formed opposite a closed proximal end.</p> <p>For example, at least the references listed below disclose a flexible elongated member including a distal end formed opposite a closed proximal end.</p> <p>U.S. Pat. No. 9,168,126 to Preissman ("Preissman '126"), Exhibit <del>12</del> at 1.1.</p> <p>U.S. Pat. App. Pub. No. 2014/0228951 to Zochowski ("Zochowski"), Exhibit <del>23</del> at 1.1.</p> <p>U.S. Pat. App. Pub. No. 2015/0032208 to Priessman ("Priessman '208"), Exhibit <del>34</del> at 1.1.</p> <p><del>U.S. Pat. No. 4,651,504 to Bentsen ("Bentsen"), Exhibit 6 at 1.1.</del></p> <p>U.S. Pat. No. 8,690,428 to Kruse ("Kruse"), Exhibit <del>58</del> at 1.1.</p> <p>U.S. Pat. No. 8,262,289 to Fratti ("Fratti"), Exhibit <del>69</del> at 1.1.</p> <p>U.S. Pat. App. Pub. No. 2007/0038310 to Guetty ("Guetty"), Exhibit <del>107</del> at 1.1.</p>
<p>[1.2] the distal end including a first longitudinal edge and a second longitudinal edge, the first longitudinal edge and second longitudinal edge further defining the longitudinal opening,</p>	<p>Ronsonet discloses this limitation:</p> <p>It is further principal object of the present invention to provide a funnel apparatus which can adjust into a plurality of sizes, so that the diameter of the end spout of the funnel can be adjustable depending on the sealing or the locking member that is sealed along the common edge.</p> <p>Ronsonet, 2:28-34.</p> <p>Sheet member 12 would be rectangular in shape having an upper first edge 14, a lower edge 16 substantially parallel to the first edge 14, a left vertical edge 18 and a right vertical edge 20 parallel with edge 18 to configure a substantially rectangular sheet as illustrated. The sheet would further comprise a forward face 22 as illustrated in FIG. 1 and a rear face 24 as illustrated in FIG. 2.</p> <p>Ronsonet, 2:62-68.</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Ronsonet
	 <p data-bbox="678 846 953 873">Ronsonet, FIG. 3 – 4.</p> <p data-bbox="732 935 1839 1403">With that locking concept in mind, reference is made now to FIGS. 3 and 4 of the apparatus, which illustrates the manner in which the apparatus is configured into a shape to function as an adjustable funnel apparatus 50 as illustrated in FIG. 4. It is quite commonplace that if one takes a substantially rectangular sheet as illustrated in FIGS. 1 and 2, that if one were to configure the positioning of the sheet as illustrated in FIG. 3, by rotating one face of the sheet in a circular fashion, that the sheet could be configured into a funnel apparatus as illustrated in FIG. 4. With that general concept in mind which is quite commonly known, reference is made to FIG. 3 where it is seen that the edge 18 of the apparatus has been formed into a circular pattern in the direction of arrow 40, and face 22 having the plurality of channel members 28 is being circulated around so that one of the parallel channel members 28 is brought into parallel locking alignment with horizontal raised locking member 38, and horizontal channel member 34 is brought into parallel locking alignment with vertical raised locking member 36</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Ronsonet
	<p>along edge 20, as illustrated in phantom view in FIG. 4. Therefore, once the locking members have been pressed into locking relationship as with a ZIPLOCK® locking arrangement, FIG. 4 would define the funnel member 50 having an upper enlarged spout area 52, a continuous annular wall portion 54 which is then sealed along a common edge 56 via locking members 28, 38 and sealed along a top edge 58 via the locking relationship of locking members 34, 36. Further, as illustrated there would be further defined a reduced downspout opening 60 which is formed as a result of the manner in which the rectangular sheet 12 is placed into the configuration as illustrated.</p> <p>Ronsonet, 3:51-4:15.</p> <p>Therefore, once the locking members have been pressed into locking relationship as with a ZIPLOCK® locking arrangement, FIG. 4 would define the funnel member 50 having an upper enlarged spout area 52, a continuous annular wall portion 54 which is then sealed along a common edge 56 via locking members 28, 38 and sealed along a top edge 58 via the locking relationship of locking members 34, 36. Further, as illustrated there would be further defined a reduced downspout opening 60 which is formed as a result of the manner in which the rectangular sheet 12 is placed into the configuration as illustrated.</p> <p>Ronsonet, 4:4-16.</p>
<p>[1.3] at least one first fastener formed on the elongated member adjacent the first longitudinal edge,</p> <p>and a second fastener formed on the elongated member adjacent the second longitudinal edge;</p> <p>[1.4] the second fastener adapted to</p>	<p>Ronsonet discloses this limitation:</p> <p>It is further principal object of the present invention to provide a funnel apparatus which can adjust into a plurality of sizes, so that the diameter of the end spout of the funnel can be adjustable depending on the sealing or the locking member that is sealed along the common edge.</p> <p>Ronsonet, 2:28-34.</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Ronsonet
<p>matingly engage with the at least first fastener and to close the longitudinal opening,</p>	<p>With that locking concept in mind, reference is made now to FIGS. 3 and 4 of the apparatus, which illustrates the manner in which the apparatus is configured into a shape to function as an adjustable funnel apparatus 50 as illustrated in FIG. 4. It is quite commonplace that if one takes a substantially rectangular sheet as illustrated in FIGS. 1 and 2, that if one were to configure the positioning of the sheet as illustrated in FIG. 3, by rotating one face of the sheet in a circular fashion, that the sheet could be configured into a funnel apparatus as illustrated in FIG. 4. With that general concept in mind which is quite commonly known, reference is made to FIG. 3 where it is seen that the edge 18 of the apparatus has been formed into a circular pattern in the direction of arrow 40, and face 22 having the plurality of channel members 28 is being circulated around so that one of the parallel channel members 28 is brought into parallel locking alignment with horizontal raised locking member 38, and horizontal channel member 34 is brought into parallel locking alignment with vertical raised locking member 36 along edge 20, as illustrated in phantom view in FIG. 4. Therefore, once the locking members have been pressed into locking relationship as with a ZIPLOCK® locking arrangement, FIG. 4 would define the funnel member 50 having an upper enlarged spout area 52, a continuous annular wall portion 54 which is then sealed along a common edge 56 via locking members 28, 38 and sealed along a top edge 58 via the locking relationship of locking members 34, 36. Further, as illustrated there would be further defined a reduced downspout opening 60 which is formed as a result of the manner in which the rectangular sheet 12 is placed into the configuration as illustrated.</p> <p>Ronsonet, 3:51-4:15.</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Ronsonet
	<div data-bbox="682 289 1717 760"> </div> <p data-bbox="682 808 955 841">Ronsonet, FIG. 3 – 4.</p> <p data-bbox="730 898 1837 1185">It should be fully understood that this particular embodiment should not be limiting in the sense that the plurality of channel member 28 do not necessarily have to be evenly spaced apart, but could be configured into a particular dimensional arrangement i.e. one inch apart or even having a plurality of channel members along face 22 which would allow one to configure the funnel in a single funnel size, or in two or three or more funnel sizes depending on the location of the channel members 28. Therefore, it is foreseen that the sheets could be formed in many configurational sizes, and not limited to the sizes as illustrated in the Figures.</p> <p data-bbox="682 1206 924 1239">Ronsonet, 4:42-53.</p> <ol data-bbox="735 1295 1753 1396" style="list-style-type: none"> <li>1. An adjustable funnel apparatus comprising: <ol style="list-style-type: none"> <li>a) a substantially flexible sheet member, having a first face and a second face;</li> </ol> </li> </ol>



Asserted Claim 1 of the '213 Patent	Exemplary Citations to Ronsonet
	<p>b) at least one first channel running substantially along the width of said first face;</p> <p>c) a second channel running along a portion of the length of the first face and substantially perpendicular to the positioning of the at least one first channel;</p> <p>d) a first raised locking member running along adjacent an edge of the second face of the sheet member;</p> <p>e) a second raised locking member running along the lower edge of the second face and substantially perpendicular to the alignment of the first locking member;</p> <p>f) means for positioning the sheet member into a configuration so that one of the at least one first channel lockingly mates with the second raised locking member and the second channel mates with the first locking member, for defining a funnel shaped apparatus sealed by the locking engagement of one of the at least one first channel and the second channel to the second and first locking members respectively.</p> <p>Ronsonet, claim 1, 4:62-5:18.</p>
<p>[1.5] whereby a predetermined size distal opening is formed based on the engagement of the second fastener with the at least one first fastener, the distal opening sized to allow the prosthetic implant to be urged therethrough.</p>	<p>Ronsonet discloses this limitation:</p> <p>It is further principal object of the present invention to provide a funnel apparatus which can adjust into a plurality of sizes, so that the diameter of the end spout of the funnel can be adjustable depending on the sealing or the locking member that is sealed along the common edge.</p> <p>Ronsonet, 2:28-34.</p> <p>Turning now to the plurality of channel members 28 as they would configure into locking relationship with raised members 34, 36, as was discussed earlier, each of the channel members 28 are positioned in parallel relationship for defining a specific dimensional distance therebetween. Therefore, this dimensional distance as defined by</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Ronsonet
	<p>the letter A in FIG. 3, results in a particular configuration of the diameter of downspout 60. Therefore, as raised locking edge 38 is configured into locking engagement with a particular channel 28, the diameter of the downspout 60 formed thereby is of a dimension in direct relation to the change in the distance between the parallel channels 28. For example, if one were to assume that the diameter of downspout 60 in FIG. 4 is 1/2 inch in the position that locking channel 28 locks with raised locking member 38, then were locking member 38 moved to the next channel 28B, as illustrated in FIG. 4, if that distance would be for example 1/4 of an inch, then the diameter of the downspout 60 would be reduced 1/4 of an inch. Therefore, with this relationship in mind, it is foreseen that the plurality of channels 28 allow one therefore to matingly engage a particular channel 28 with locking member 38, depending on the diameter of downspout 60 that one wishes to achieve in the final configuration of funnel member 50.</p> <p>Ronsonet, 4:16-41.</p> <p>The intended use of the device of claim 1, the type of object for insertion, and the size of the object are not material limitations.</p> <p><del>To the extent NovaPlast alleges that this limitation is not expressly or inherently disclosed in Ronsonet, it would have been obvious in light of the knowledge of a person of ordinary skill in the art. A person of ordinary skill in the art would have been motivated to combine Ronsonet with any of the other references identified in Defendants' Initial Invalidity Contentions regarding the '213 Patent at least to the extent they desired to provide a device with a longitudinal opening that is closed by a first and second fastener, whereby engagement of the first and second fasteners forms a predetermined size distal opening that is sized to allow a prosthetic implant to be urged therethrough.</del></p> <p><del>For example, at least the references listed below disclose a device with a longitudinal opening that is closed by a first and second fastener, whereby engagement of the first and second fasteners forms a predetermined size distal opening that is sized to allow a prosthetic implant to be urged therethrough.</del></p> <p><del>U.S. Pat. No. 5,121,779 to Green ("Green"), Exhibit 1 at 1.5.</del></p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Ronsonet
	<p>U.S. Pat. No. 9,168,126 to Preissman ("Preissman '126"), Exhibit 2 at 1.5.</p> <p>U.S. Pat. App. Pub. No. 2014/0228951 to Zochowski ("Zochowski"), Exhibit 3 at 1.5.</p> <p>U.S. Pat. App. Pub. No. 2015/0032208 to Priessman ("Priessman '208"), Exhibit 4 at 1.5.</p> <p>U.S. Pat. No. 4,651,504 to Bentsen ("Bentsen"), Exhibit 6 at 1.5.</p> <p>U.S. Pat. No. 4,825,915 to Hess ("Hess"), Exhibit 7 at 1.5.</p> <p>U.S. Pat. No. 8,690,428 to Kruse ("Kruse"), Exhibit 8 at 1.5.</p> <p>U.S. Pat. No. 8,262,289 to Fratti ("Fratti"), Exhibit 9 at 1.5.</p> <p>U.S. Pat. App. Pub. No. 2007/0038310 to Guetty ("Guetty"), Exhibit 10 at 1.5.</p>

**CLAIM 5**

<b>Asserted Claim of the '213 Patent</b>	<b>Exemplary Citations to Ronsonet</b>
<p>[5.0] 5. The delivery system of claim 1, each of the at least one first, fastener further comprising a channel, the second fastener defining a shoulder, the shoulder adapted to be received within and secured with the channel of at least one of the first fasteners.</p>	<p>Ronsonet discloses the system of claim 1 <u>as set forth above with respect to claim 1, and the further recitations of this limitation:</u></p> <p><u>Ronsonet discloses a plurality of first fasteners adjacent to a longitudinal edge of a longitudinal opening, wherein the first fasteners are channels, and a second fastener comprising a shoulder adjacent to a second longitudinal edge of the longitudinal opening. Additionally Ronsonet discloses that the shoulder is adapted to matingly engage within any one of the channels defining the first fasteners and thereby define a distal opening having a size corresponding to the particular channel engaged by the shoulder.</u></p> <p>What is provided is an apparatus which includes a rectangular sheet of flexible plastic, the first face of the sheet which includes a plurality of parallel spaced apart channels, and on the second face of the sheet including a pair of raised members, one raised member positioned substantially along a first edge of the sheet, and the second raised member positioned substantially perpendicular thereto along the bottom edge of the sheet, so that when the sheet is configured into a funnel shape, one of the raised locking members is mated into the channel members, to form a sealed juncture thereon, and for defining a sealed cone having an enlarged upper end and a reduced lower spout end, defining an overall funnel member.</p> <p>Ronsonet, 1:64-2:9</p> <p><u>It is further principal object of the present invention to provide a funnel apparatus which can adjust into a plurality of sizes, so that the diameter of the end spout of the funnel can be adjustable depending on the sealing or the locking member that is sealed along the common edge.</u></p> <p><u>Ronsonet, 2:28-34.</u></p>

Asserted Claim of the '213 Patent	Exemplary Citations to Ronsonet
	<p>With that locking concept in mind, reference is made now to FIGS. 3 and 4 of the apparatus, which illustrates the manner in which the apparatus is configured into a shape to function as an adjustable funnel apparatus 50 as illustrated in FIG. 4. It is quite commonplace that if one takes a substantially rectangular sheet as illustrated in FIGS. 1 and 2, that if one were to configure the positioning of the sheet as illustrated in FIG. 3, by rotating one face of the sheet in a circular fashion, that the sheet could be configured into a funnel apparatus as illustrated in FIG. 4. With that general concept in mind which is quite commonly known, reference is made to FIG. 3 where it is seen that the edge 18 of the apparatus has been formed into a circular pattern in the direction of arrow 40, and face 22 having the plurality of channel members 28 is being circulated around so that one of the parallel channel members 28 is brought into parallel locking alignment with horizontal raised locking member 38, and horizontal channel member 34 is brought into parallel locking alignment with vertical raised locking member 36 along edge 20, as illustrated in phantom view in FIG. 4. Therefore, once the locking members have been pressed into locking relationship as with a ZIPLOCK® locking arrangement, FIG. 4 would define the funnel member 50 having an upper enlarged spout area 52, a continuous annular wall portion 54 which is then sealed along a common edge 56 via locking members 28, 38 and sealed along a top edge 58 via the locking relationship of locking members 34, 36. Further, as illustrated there would be further defined a reduced downspout opening 60 which is formed as a result of the manner in which the rectangular sheet 12 is placed into the configuration as illustrated.</p> <p>Ronsonet, 3:51-4:15.</p>

Asserted Claim of the '213 Patent	Exemplary Citations to Ronsonet
	<div data-bbox="688 289 1717 760"> </div> <p data-bbox="678 808 953 841">Ronsonet, FIG. 3 – 4.</p> <p data-bbox="735 898 1837 1190">It should be fully understood that this particular embodiment should not be limiting in the sense that the plurality of channel member 28 do not necessarily have to be evenly spaced apart, but could be configured into a particular dimensional arrangement i.e. one inch apart or even having a plurality of channel members along face 22 which would allow one to configure the funnel in a single funnel size, or in two or three or more funnel sizes depending on the location of the channel members 28. Therefore, it is foreseen that the sheets could be formed in many configurational sizes, and not limited to the sizes as illustrated in the Figures.</p> <p data-bbox="678 1206 919 1239">Ronsonet, 4:42-53.</p> <ol data-bbox="735 1295 1745 1401" style="list-style-type: none"> <li>1. An adjustable funnel apparatus comprising:       <ol style="list-style-type: none"> <li>a) a substantially flexible sheet member, having a first face and a second face;</li> </ol> </li> </ol>

Asserted Claim of the '213 Patent	Exemplary Citations to Ronsonet
	<p>b) at least one first channel running substantially along the width of said first face;</p> <p>c) a second channel running along a portion of the length of the first face and substantially perpendicular to the positioning of the at least one first channel;</p> <p>d) a first raised locking member running along adjacent an edge of the second face of the sheet member;</p> <p>e) a second raised locking member running along the lower edge of the second face and substantially perpendicular to the alignment of the first locking member;</p> <p>f) means for positioning the sheet member into a configuration so that one of the at least one first channel lockingly mates with the second raised locking member and the second channel mates with the first locking member, for defining a funnel shaped apparatus sealed by the locking engagement of one of the at least one first channel and the second channel to the second and first locking members respectively.</p> <p>Ronsonet, claim 1, 4:62-5:18.</p>

## Exhibit 58

### U.S. Pat. No. 10,105,213 in view of U.S. Pat. No. 8,690,428 to Kruse (“Kruse”)

As described in detail below, Kruse anticipates and/or renders obvious claims 1 and 5 of U.S. Patent No. 10,105,213 to Weinzweig (the “213 Patent” or “Patent-in-Suit”), which was filed on December 29, 2015 and issued on October 23, 2018, (collectively, the “Asserted Claims”) under 35 U.S.C. § 102 and/or § 103, either alone or in combination with other prior art references, and/or in combination with the knowledge of a person of ordinary skill. Kruse anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit as those claims have been applied by Plaintiff NovaPlast Corporation (“NovaPlast” or “Plaintiff”) in its Infringement Contentions and/or as construed by the Court in its [Markman] Opinion & Order dated July 26, 2023 (Dkt. 73) (the “Markman Order”)~~under Defendants’ understanding of the proper construction of the claims.~~ To the extent it is found Kruse or the additional references cited herein do~~does~~ not expressly disclose certain limitations in the asserted claim, such limitations are inherent.

Kruse was originally filed on Nov. 12, 2009 and issued on Apr. 8, 2014, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Kruse. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Kruse (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Kruse and/or its prior art status, as evidence that the technology described in Kruse anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

The cited portions of Kruse are merely illustrative, and Defendants reserve the right to rely on alternative or additional evidence, including uncited portions of Kruse. Where the chart below states that Kruse “describes,” “discloses,” or “provides for” a limitation, such disclosure may be express, inherent, or implicit. If not anticipated, one or more claims of the Patent-in-Suit are rendered obvious in light of Kruse alone or Kruse in combination with other prior art references and/or with the knowledge of a person of ordinary skill in the art.

This chart is subject to all reservations, objections, and disclaimers in Defendants’ ~~Initial~~ Amended Invalidity Contentions and any amendment, supplement, or modification thereof, which are incorporated herein by reference in their entirety. Nothing stated herein shall be treated as an admission or suggestion that Defendants agree with NovaPlast regarding either the scope of the Asserted Claims or the claim constructions advanced by NovaPlast in its Infringement Contentions or anywhere else, or that any of Defendants’ accused products meet any limitation of the Asserted Claims. ~~Nothing stated herein shall be construed as an admission or a waiver of any particular construction of any claim term.~~ Nothing stated herein shall be construed as an admission that the Asserted Claims are directed to patent-eligible subject matter. Defendants also reserve all rights to challenge any of the claim terms herein under 35 U.S.C. § 112,

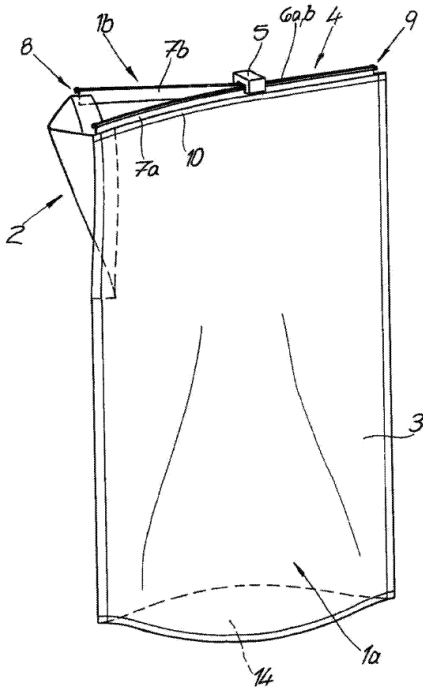


including by arguing that they are indefinite, not supported by the written description, and/or not enabled. Nothing stated herein shall be construed as an admission or waiver with respect to the effective filing date of the Asserted Claims.

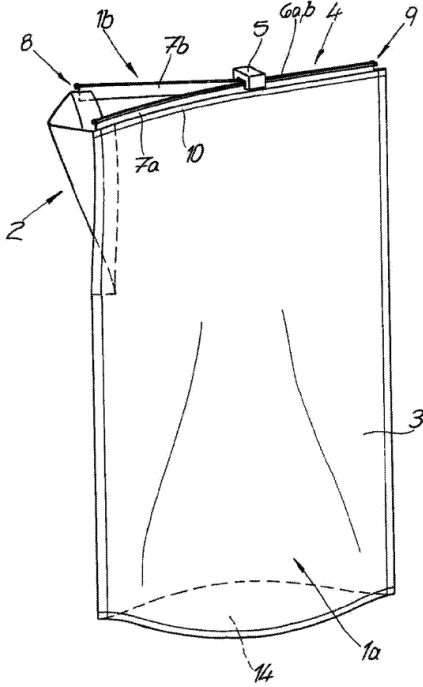
**U.S. Pat. No. 10,105,213 in view of  
U.S. Pat. No. 8,690,428 to Kruse (“Kruse”)**

**CLAIM 1**

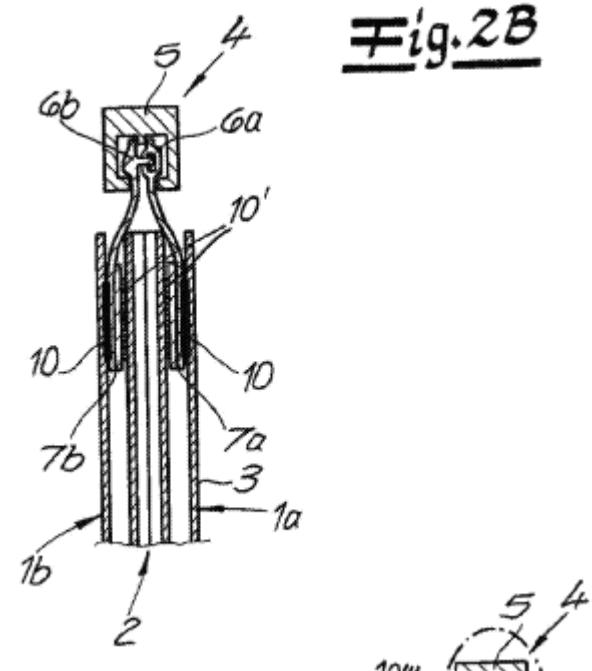
<b>Asserted Claim 1 of the ‘213 Patent</b>	<b>Exemplary Citations to Kruse</b>
[1.p] 1. A delivery system adapted to facilitate insertion of a prosthetic implant through a surgical opening, the system comprising:	<p>To the extent the preamble is limiting, Kruse discloses this limitation:</p> <p style="padding-left: 40px;">The present invention relates to a plastic packaging bag for holding pourable material. More particularly this invention concerns such a bag having a pour spout and a slide closure.</p> <p>Kruse, 1:5-9.</p>
[1.1] a flexible elongated member defining a proximal end and a distal end, the proximal end formed opposite the distal end and defining a closed end, the distal end defining a longitudinal opening;	Kruse discloses this limitation:

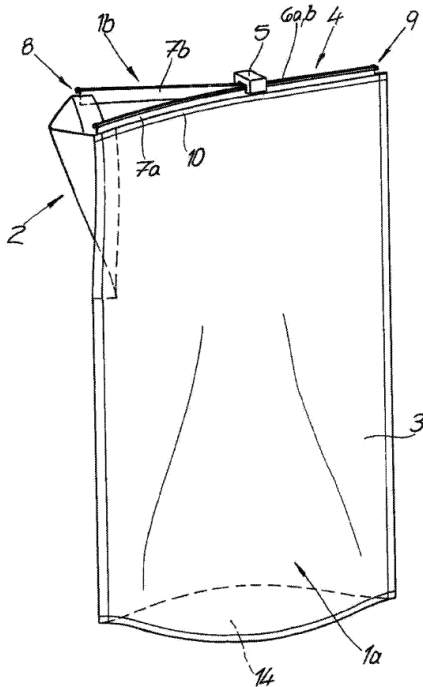
Asserted Claim 1 of the '213 Patent	Exemplary Citations to Kruse
	<p><u>Fig. 4</u></p>  <p>Kruse, FIG. 4</p> <p>As seen in FIG. 1 a bag according to the invention is formed as a side-gusset bag having two rectangular face panels 1a and 1b positioned opposite each other, and two gussets 2 and 2' connecting normally vertical side edges of the face panels 1a and 1b. Without limitation the bag may be formed from individual sections or preferably by folds and seals from a single piece of film 3.</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Kruse
	Kruse, 5:14-20.
[1.2] the distal end including a first longitudinal edge and a second longitudinal edge, the first longitudinal edge and second longitudinal edge further defining the longitudinal opening,	<p>Kruse discloses this limitation:</p> <p><u>Kruse discloses a bag having a pour spout opening at a distal end thereof. Kruse discloses an opening extending longitudinally from the pour spout in a longitudinal direction to a proximal end of the bag. The longitudinal opening is defined by the upper edges of opposing face panels (1a and 1b).</u></p> <p>FIG. 4 shows an alternative embodiment of the bag as a standup bag with a gusset 2 made from a separate piece of film inserted at the first end 8 of the slide fastener 4 and extending only across a portion of the bag end. The face panels 1a and 1b are connected directly to each other at a lower end of the bag underneath the gusset 2 and at the opposite edge of the bag. A separate piece of film 14 is provided as the standup base of the bag. The gusset 2 inserted at the upper end only serves to enable easier emptying, and particularly for precise dosing, and does not contribute to increasing the fill capacity. Thus the height and depth of the gusset 2 may be selected according to ergonomic considerations regardless of the intended contents.</p> <p>Since the slide fastener 4 extends across the entire width of the face panels 1a and 1b, a quick and complete emptying of the bag is also possible. As in the embodiment according to FIGS. 1 to 2c described above it may also be provided that the slide fastener 4, based on the extendable gusset 2 forming a spout, extends only across part of the face panels 1a and 1b, such as approximately up to the center of the face panels 1a and 1b. Due to the fact that the discharge opening is significantly enlarged because of the extending of the gusset 2, only a comparatively short slide fastener 4 is necessary according to the invention for good handling, particularly if no uncontrolled, complete emptying of the bag needs to occur. Therefore, a precise controlling of the contents is usually necessary when pouring the contents out of the bag such that a complete opening on the top is often not required or desired.</p> <p>Kruse, 6:34-61.</p>

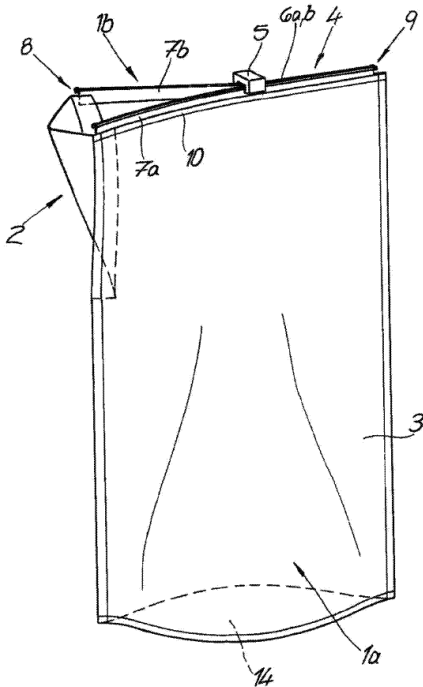
Asserted Claim 1 of the '213 Patent	Exemplary Citations to Kruse
	<p><u>Fig. 4</u></p>  <p>Kruse, FIG. 4.</p>
<p>[1.3] at least one first fastener formed on the elongated member adjacent the first longitudinal edge,</p> <p>and a second fastener formed on the elongated member adjacent the second longitudinal edge;</p>	<p>Kruse discloses this limitation:</p> <p><u>Kruse discloses that a slide fastener comprising opposing structures formed adjacent to the upper edges of face panels 1a and 1b respectively and configured to engage and thereby close the longitudinal opening. Kruse, 1:4.</u></p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Kruse
<p>[1.4] the second fastener adapted to matingly engage with the at least first fastener and to close the longitudinal opening,</p>	<p>A slide fastener 4 is provided at the horizontal upper end of the bag defined by upper edges of the panels 1a and 1b and extends across the entire width of the face panels 1a and 1b. The slide fastener 4 comprises a gripper-type slider 5, two profile strips 6a and 6b that can be locked to each other by the slider 5 and that carry attachment flaps 7a and 7b that connect the slide fastener 4 to the bag film 3 on inner surfaces of the bag. FIG. 1 shows the slide fastener 4 in the closed position with the slider 5 at a first end 8 of the slide fastener 4. Here the first end 8 blocks movement of the slider 5 along the profile strips 6a and 6b in a first closing direction. Opposite movement of the slider 5 in a second opening direction separates the profile strips 6a and 6b that were initially locked to each other to open the slide fastener 4.</p> <p>In the illustrated closed position of the slide fastener 4, the gusset 2 is closed, e.g. covered, along its upper edge by the connected profile strips 6a and 6b above it. FIG. 3 shows the film package bag with an opened slide fastener 4 and the slider at a second end 9 of the slide fastener at which the profile strips 6a and 6b and optionally also the attachment flaps 7a and 7b are permanently connected to each other, such as by welding. In case of an open slide fastener 4, the gusset 2 at the first end 8 of the slide fastener 4 may be extended to form a spout, thus enabling simple and accurate pouring of the contents from the bag. Extension of the gusset 2 is even possible with a partial opening of the slide fastener 4 such that the size of the dispensing opening may be freely selected.</p> <p>Kruse, 5:14-47.</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Kruse
	<p data-bbox="1071 284 1270 365"><u>Fig. 2B</u></p>  <p data-bbox="682 966 892 998">Kruse, FIG. 2B.</p>

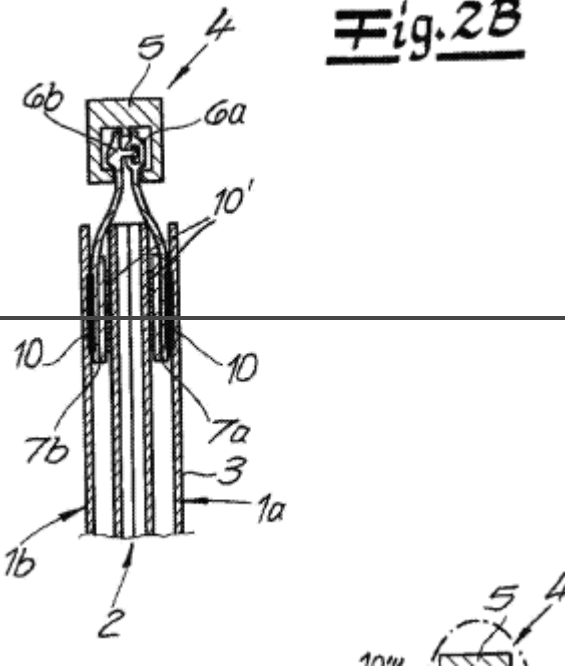
Asserted Claim 1 of the '213 Patent	Exemplary Citations to Kruse
	<p><u>Fig. 4</u></p>  <p>Kruse, FIG. 4.</p>
<p>[1.5] whereby a predetermined size distal opening is formed based on the engagement of the second fastener with the at least one first fastener, the distal opening sized to allow the prosthetic implant to be urged therethrough.</p>	<p>Kruse discloses this limitation:</p> <p>Kruse discloses a predetermined size distal opening that is sized to allow materials, which can include a prosthetic implant, to be urged therethrough. Kruse also discloses the distal opening being formed based on the engagement of fasteners that join longitudinal edges of the flexible material.</p>



Asserted Claim 1 of the '213 Patent	Exemplary Citations to Kruse
	<p><u>Fig. 4</u></p>  <p>Kruse, FIG. 4.</p> <p>FIG. 4 shows an alternative embodiment of the bag as a standup bag with a gusset 2 made from a separate piece of film inserted at the first end 8 of the slide fastener 4 and extending only across a portion of the bag end. The face panels 1a and 1b are connected directly to each other at a lower end of the bag underneath the gusset 2 and at the opposite edge of the bag. A separate piece of film 14 is provided as the standup base of the bag. The gusset 2 inserted at the upper end only serves to enable easier emptying, and particularly for precise dosing, and does not contribute to increasing the fill</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Kruse
	<p>capacity. Thus the height and depth of the gusset 2 may be selected according to ergonomic considerations regardless of the intended contents.</p> <p>Since the slide fastener 4 extends across the entire width of the face panels 1a and 1b, a quick and complete emptying of the bag is also possible. As in the embodiment according to FIGS. 1 to 2c described above it may also be provided that the slide fastener 4, based on the extendable gusset 2 forming a spout, extends only across part of the face panels 1a and 1b, such as approximately up to the center of the face panels 1a and 1b. Due to the fact that the discharge opening is significantly enlarged because of the extending of the gusset 2, only a comparatively short slide fastener 4 is necessary according to the invention for good handling, particularly if no uncontrolled, complete emptying of the bag needs to occur. Therefore, a precise controlling of the contents is usually necessary when pouring the contents out of the bag such that a complete opening on the top is often not required or desired.</p> <p>Kruse, 6:34-61.</p> <p><u>The structure of Kruse is configured such that closing the longitudinal opening using the fasteners forms a distal end opening (e.g., pour spout) of a predetermined size. Moreover, the size of the distal end opening (e.g., pour spout) of Kruse is suitable for a prosthetic implant to be urged therethrough.</u></p> <p>The intended use of the device of claim 1, the type of object for insertion, and the size of the object are not material limitations.</p>

**CLAIM 5**

<b>Asserted Claim— of the '213 Patent</b>	<b>Exemplary Citations to Kruse</b>
<p>[5.0] 5. The delivery system of claim 1, each of the at least one first, fastener further comprising a channel, the second fastener defining a shoulder, the shoulder adapted to be received within and secured with the channel of at least one of the first fasteners.</p>	<p>Kruse discloses this limitation:</p>  <p><b>Fig. 2B</b></p> <p>Kruse, FIG. 2B.</p> <p>A slide fastener 4 is provided at the horizontal upper end of the bag defined by upper edges of the panels 1a and 1b and extends across the entire width of the face panels 1a and 1b. The slide fastener 4 comprises a gripper-type slider 5, two profile strips 6a and 6b that can be locked to each other by the slider 5 and that carry attachment flaps 7a and 7b that connect the slide fastener 4 to the bag film 3 on inner surfaces of the bag.</p>

Asserted Claim of the '213 Patent	Exemplary Citations to Kruse
	<p>FIG. 1 shows the slide fastener 4 in the closed position with the slider 5 at a first end 8 of the slide fastener 4. Here the first end 8 blocks movement of the slider 5 along the profile strips 6a and 6b in a first closing direction. Opposite movement of the slider 5 in a second opening direction separates the profile strips 6a and 6b that were initially locked to each other to open the slide fastener 4.</p> <p>In the illustrated closed position of the slide fastener 4, the gusset 2 is closed, e.g. covered, along its upper edge by the connected profile strips 6a and 6b above it. FIG. 3 shows the film package bag with an opened slide fastener 4 and the slider at a second end 9 of the slide fastener at which the profile strips 6a and 6b and optionally also the attachment flaps 7a and 7b are permanently connected to each other, such as by welding. In case of an open slide fastener 4, the gusset 2 at the first end 8 of the slide fastener 4 may be extended to form a spout, thus enabling simple and accurate pouring of the contents from the bag. Extension of the gusset 2 is even possible with a partial opening of the slide fastener 4 such that the size of the dispensing opening may be freely selected.</p> <p>Kruse, 5:14-47.</p>

## Exhibit 96

### U.S. Pat. No. 10,105,213 in view of U.S. Pat. No. 8,262,289 to Fratti (“Fratti”)

As described in detail below, Fratti anticipates and/or renders obvious claims 1 and 5 of U.S. Patent No. 10,105,213 to Weinzweig (the “213 Patent” or “Patent-in-Suit”), which was filed on December 29, 2015 and issued on October 23, 2018, (collectively, the “Asserted Claims”) under 35 U.S.C. § 102 and/or § 103, either alone or in combination with other prior art references, and/or in combination with the knowledge of a person of ordinary skill. Fratti anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit as those claims have been applied by Plaintiff NovaPlast Corporation (“NovaPlast” or “Plaintiff”) in its Infringement Contentions and/or as construed by the Court in its [Markman] Opinion & Order dated July 26, 2023 (Dkt. 73) (the “Markman Order”)~~under Defendants’ understanding of the proper construction of the claims.~~ To the extent it is found Fratti or the additional references cited herein do~~does~~ not expressly disclose certain limitations in the asserted claim, such limitations are inherent.

Fratti was originally filed on Jan. 31, 2007 and issued on Sept. 11, 2012, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Fratti. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Fratti (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Fratti and/or its prior art status, as evidence that the technology described in Fratti anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

The cited portions of Fratti are merely illustrative, and Defendants reserve the right to rely on alternative or additional evidence, including uncited portions of Fratti. Where the chart below states that Fratti “describes,” “discloses,” or “provides for” a limitation, such disclosure may be express, inherent, or implicit. If not anticipated, one or more claims of the Patent-in-Suit are rendered obvious in light of Fratti alone or Fratti in combination with other prior art references and/or with the knowledge of a person of ordinary skill in the art.

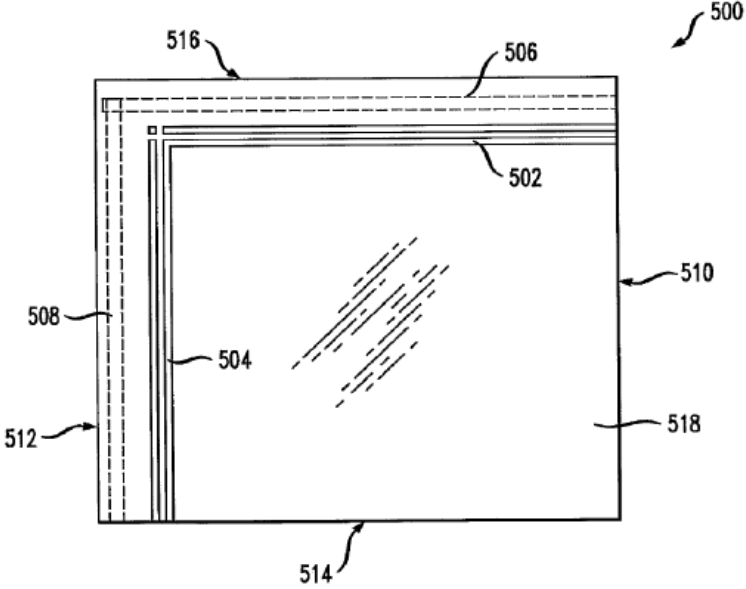
This chart is subject to all reservations, objections, and disclaimers in Defendants’ ~~Initial~~ Amended Invalidity Contentions and any amendment, supplement, or modification thereof, which are incorporated herein by reference in their entirety. Nothing stated herein shall be treated as an admission or suggestion that Defendants agree with NovaPlast regarding either the scope of the Asserted Claims or the claim constructions advanced by NovaPlast in its Infringement Contentions or anywhere else, or that any of Defendants’ accused products meet any limitation of the Asserted Claims. ~~Nothing stated herein shall be construed as an admission or a waiver of any particular construction of any claim term.~~ Nothing stated herein shall be construed as an admission that the Asserted Claims are directed to patent-eligible subject matter. Defendants also reserve all rights to challenge any of the claim terms herein under 35 U.S.C. § 112,

including by arguing that they are indefinite, not supported by the written description, and/or not enabled. Nothing stated herein shall be construed as an admission or waiver with respect to the effective filing date of the Asserted Claims.

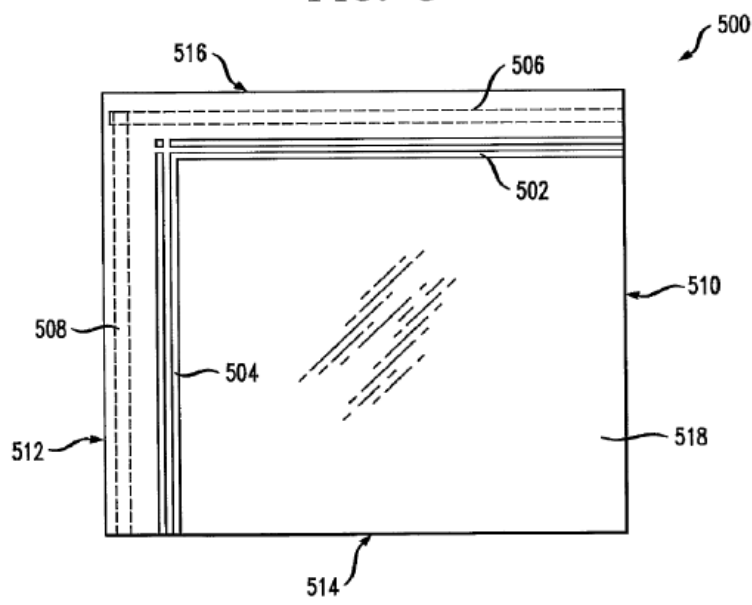
**U.S. Pat. No. 10,105,213 in view of  
U.S. Pat. No. 8,262,289 to Fratti (“Fratti”)**

**CLAIM 1**

<b>Asserted Claim 1 of the ‘213 Patent</b>	<b>Exemplary Citations to Fratti</b>
<p>[1.p] 1. A delivery system adapted to facilitate insertion of a prosthetic implant through a surgical opening, the system comprising:</p>	<p>To the extent the preamble is limiting, Fratti discloses this limitation:</p> <p style="padding-left: 40px;">The present invention relates generally to bag-type containers, and more particularly to closure mechanisms for resealable bag-type containers.</p> <p>Fratti, 1:6-8.</p> <p><u>The structure of the bag-type container device disclosed in Fratti is capable of receiving a prosthetic implant therein, dispensing the prosthetic implant out of an opening and facilitating the insertion of a prosthetic implant through a surgical opening.</u></p>
<p>[1.1] a flexible elongated member defining a proximal end and a distal end, the proximal end formed opposite the distal end and defining a closed end, the distal end defining a longitudinal opening;</p>	<p>Fratti discloses this limitation:</p> <p style="padding-left: 40px;">FIG. 5 is a side view depicting an exemplary bag-type container 500, formed in accordance with another embodiment of the invention. Bag-type container 500 preferably includes at least one additional pair of closure mechanisms disposed along a periphery of at least a portion of a second edge of the container. The access opening or mouth of bag-type container 500 is thus provided along adjacent edges (e.g., side edge 512 and top edge 516) of the container. Wall panels of bag-type container 500 (of which only one wall panel, 518, is shown for clarity) are joined together or integral along at least a portion of bottom edge 514 and side edge 510. The larger opening beneficially facilitates inserting bulky, unwieldy items into bag-type container 500.</p> <p>Fratti, 6:40-52.</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Fratti
	<p style="text-align: center;"><i>FIG. 5</i></p>  <p>Fratti, FIG. 5.</p> <p>Bag-type container 100 is preferably fabricated from a suitable plastic film or sheet material, as is common in this art, although the invention is not limited to the type of material employed.</p> <p>Fratti, 4:50-54</p>
[1.2] the distal end including a first longitudinal edge and a second longitudinal edge, the first longitudinal edge and second	Fratti discloses this limitation:

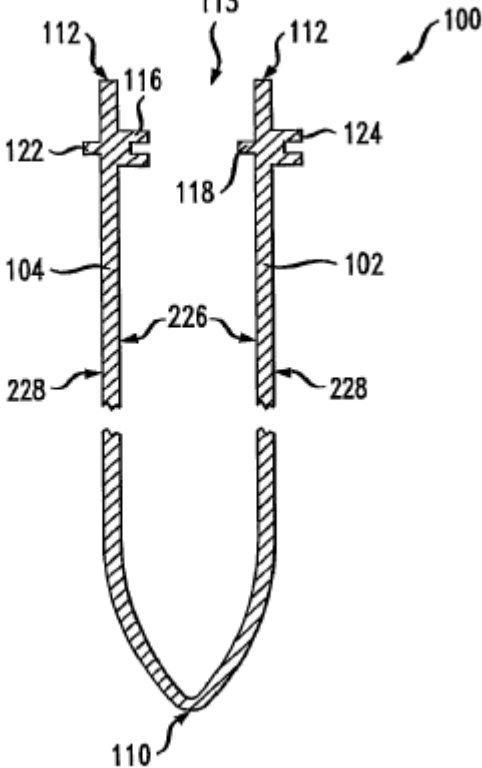


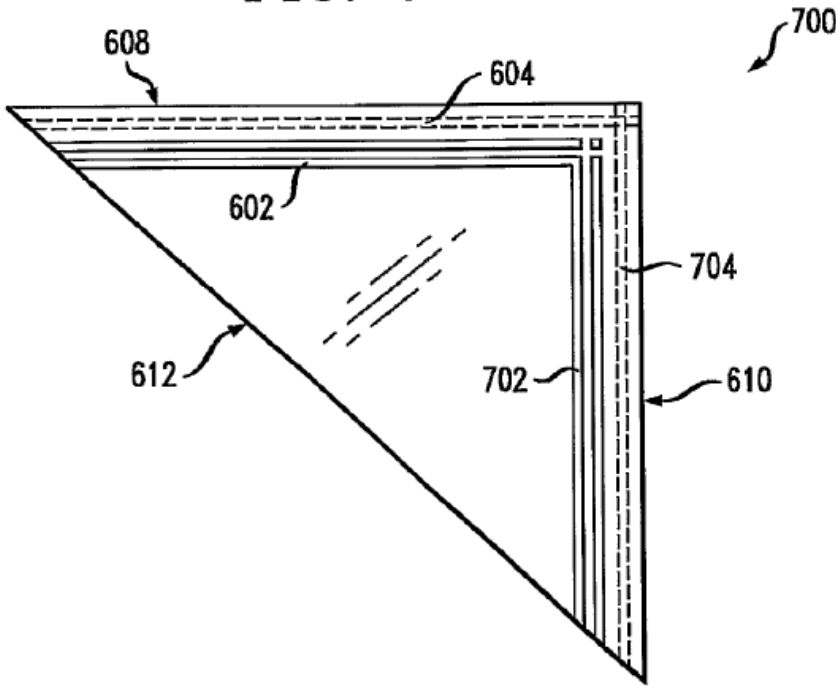
Asserted Claim 1 of the '213 Patent	Exemplary Citations to Fratti
longitudinal edge further defining the longitudinal opening,	<p style="text-align: center;"><b>FIG. 5</b></p>  <p>Fratti, FIG. 5.</p> <p>FIG. 5 is a side view depicting an exemplary bag-type container 500, formed in accordance with another embodiment of the invention. Bag-type container 500 preferably includes at least one additional pair of closure mechanisms disposed along a periphery of at least a portion of a second edge of the container. The access opening or mouth of bag-type container 500 is thus provided along adjacent edges (e.g., side edge 512 and top edge 516) of the container. Wall panels of bag-type container 500 (of which only one wall panel, 518, is shown for clarity) are joined together or integral along at least a portion of bottom edge 514 and side edge 510. The larger opening beneficially facilitates inserting bulky, unwieldy items into bag-type container 500.</p> <p>Fratti, 6:40-65.</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Fratti
<p>[1.3] at least one first fastener formed on the elongated member adjacent the first longitudinal edge,</p> <p>and a second fastener formed on the elongated member adjacent the second longitudinal edge;</p> <p>[1.4] the second fastener adapted to matingly engage with the at least first fastener and to close the longitudinal opening,</p>	<p>Fratti discloses this limitation:</p> <div data-bbox="682 475 1425 1104"> <p style="text-align: center;"><b>FIG. 5</b></p> </div> <p>Fratti, FIG. 5.</p> <p>FIG. 5 is a side view depicting an exemplary bag-type container 500, formed in accordance with another embodiment of the invention. Bag-type container 500 preferably includes at least one additional pair of closure mechanisms disposed along a periphery of at least a portion of a second edge of the container. The access opening or mouth of bag-type container 500 is thus provided along adjacent edges (e.g., side</p>

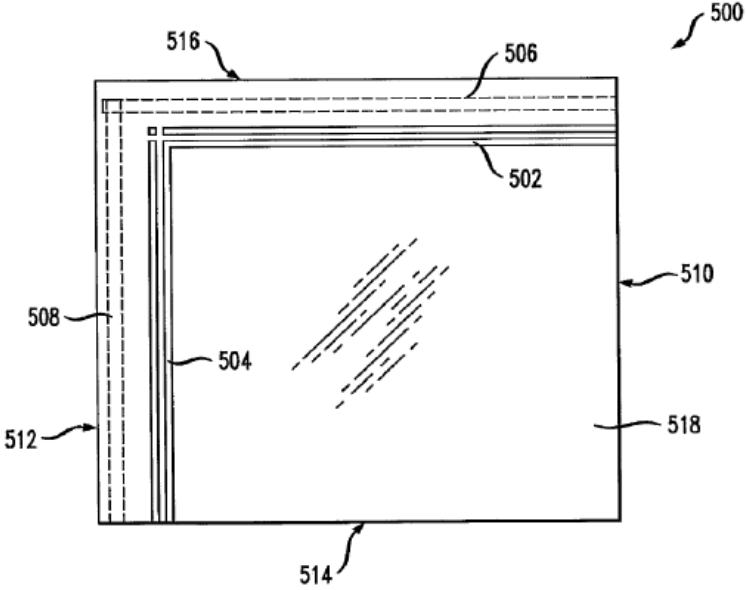
Asserted Claim 1 of the '213 Patent	Exemplary Citations to Fratti
	<p>edge 512 and top edge 516) of the container. Wall panels of bag-type container 500 (of which only one wall panel, 518, is shown for clarity) are joined together or integral along at least a portion of bottom edge 514 and side edge 510. The larger opening beneficially facilitates inserting bulky, unwieldy items into bag-type container 500.</p> <p>Specifically, bag-type container 500 includes a reversible fastener comprising at least a first closure mechanism 502 disposed along at least a portion of a top edge 516 of the container on an exterior face of each a pair of wall panels forming the container. The reversible fastener further includes a second closure mechanism 504 disposed along at least a portion of a first side edge 512 of bag-type container 500 on the exterior face of each of the wall panels, a third closure mechanism 506 disposed along at least a portion of top edge 516 on an interior face of each of the wall panels, and a fourth closure mechanism 508 disposed along at least a portion of the first side edge 512 of the container on the interior face of each of the wall panels.</p> <p>Each of the closure mechanisms 502, 504, 506, 508 preferably comprises at least first and second complementary interlockable components adapted for mutually facilitating alignment and interlocking closure engagement with one another in order to seal bag-type container 500, for example in a manner similar to that described above in connection with bag-type container 100 shown in FIG. 1. When used in a standard manner, bag-type container 500 may be sealed by engaging third and fourth closure mechanism 506 and 508, respectively, disposed on interior faces of the wall panels along top edge 516 and side edge 512. Likewise, bag-type container 500 is relatively easily opened from top edge 516 and side edge 512 by separating manipulation of the first and second complementary interlockable components of third and fourth closure mechanisms 506 and 508, respectively. First and second closure mechanisms 502 and 504, respectively, may be used for stacking multiple bag-type containers together, in a manner similar to that described above in connection with FIGS. 4A and 4B. When the bag-type container 500 is turned inside out, first and second closure mechanisms 502 and 504, respectively, are used to control access to the interior of the container, and third and fourth closure mechanisms 506 and 508, respectively, may be used for</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Fratti
	<p>stacking multiple containers together.</p> <p>Fratti, 6:40-7:22.</p> <p>The access opening 113 of bag-type container 100 is adapted to be closed and opened by a reversible fastener comprising at least first and second separable and resealable closure mechanisms 114 and 120, respectively. The reversible fastener preferably runs along substantially the entire length of the top edge 112 of the container. First closure mechanism 114 is preferably provided along at least a portion of the top edge 112 of the container. First closure mechanism 114 preferably includes first and second complementary interlockable components 116 and 118, respectively, which can be coupled together or interlocked. First complementary interlockable component 116 is disposed on an interior face of wall panel 104 proximate the top edge 112. Likewise, second complementary interlockable component 118 is disposed on an interior face of opposing wall panel 102 proximate the top edge 112. First and second complementary interlockable components 116, 118 may be formed integrally with their respective wall panels, 104, 102, such as, for example, by extrusion. Alternatively, first and second complementary interlockable components 116, 118 may be affixed to their respective wall panels, 104, 102, for example by fusing, adhesive, or some other attachment means. It is to be understood, however, that the invention is not limited to the method of forming the first and second complementary interlockable components 116, 118 on wall panels 104, 102.</p> <p>Fratti, 3:40-64.</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Fratti
	<p data-bbox="709 289 865 328"><i>FIG. 2</i></p>  <p data-bbox="678 1105 856 1138">Fratti, FIG. 2.</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Fratti
	<p style="text-align: center;"><b>FIG. 7</b></p>  <p>Fratti, FIG. 7.</p> <p>FIG. 7 is a side view illustrating an exemplary bag-type container 700, formed in accordance with an embodiment of the present invention. As apparent from the figure, bag-type container 700 is essentially the same as container 600 shown in FIG. 6, except that the reversible fastener comprises an additional pair of closure mechanisms, 702 and 704, disposed along at least a portion of first edge 610. Specifically, in addition to first and second closure mechanisms 602 and 604, respectively, disposed along top edge 608, bag-type container 700 further includes a third closure mechanism 702 disposed on an exterior face of each of the wall panels along at least a portion of first</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Fratti
	<p>edge 610, and a fourth closure mechanism 704 disposed on an interior face of each of the wall panels along at least a portion of the first edge.</p> <p>Each of the closure mechanisms 602, 604, 702 and 704 preferably comprises at least first and second complementary interlockable components adapted for mutually facilitating alignment and interlocking closure engagement with one another in order to seal bag-type container 700, for example in a manner similar to that described above in connection with bag-type container 100 shown in FIG. 1.</p> <p>Fratti, 7:57-8:10.</p>
<p>[1.5] whereby a predetermined size distal opening is formed based on the engagement of the second fastener with the at least one first fastener, the distal opening sized to allow the prosthetic implant to be urged therethrough.</p>	<p>Fratti discloses this limitation:</p> <p>FIG. 5 is a side view depicting an exemplary bag-type container 500, formed in accordance with another embodiment of the invention. Bag-type container 500 preferably includes at least one additional pair of closure mechanisms disposed along a periphery of at least a portion of a second edge of the container. The access opening or mouth of bag-type container 500 is thus provided along adjacent edges (e.g., side edge 512 and top edge 516) of the container. Wall panels of bag-type container 500 (of which only one wall panel, 518, is shown for clarity) are joined together or integral along at least a portion of bottom edge 514 and side edge 510. The larger opening beneficially facilitates inserting bulky, unwieldy items into bag-type container 500.</p> <p>Fratti, 6:40-52.</p> <p><u>The structure of Fratti is capable of having an open distal end 512, and having its longitudinal side (e.g., 512) opening closed using fasteners and thereby defines a structure having a distal end opening of a predetermined size. Moreover, the size of the distal end opening (e.g., 512) is suitable for a prosthetic implant to be urged therethrough.</u></p>

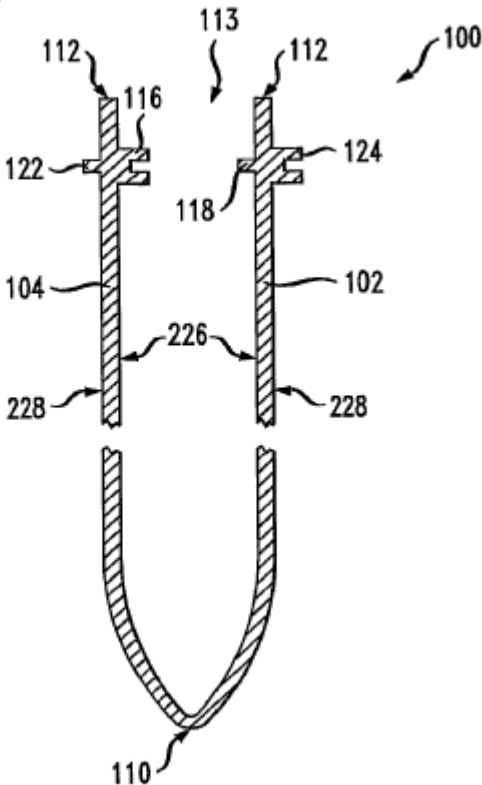
Asserted Claim 1 of the '213 Patent	Exemplary Citations to Fratti
	<p style="text-align: center;"><i>FIG. 5</i></p>  <p>Fratti, FIG. 5.</p> <p>The intended use of the device of claim 1, the type of object for insertion, and the size of the object are not material limitations.</p>

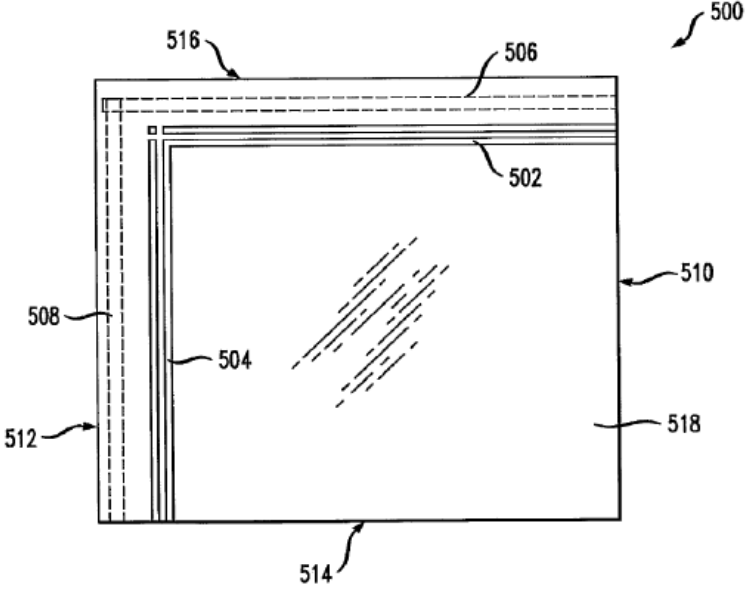


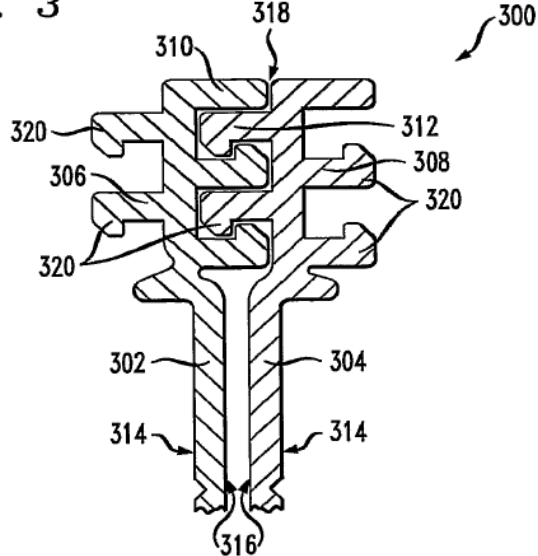
**CLAIM 5**

<b>Asserted Claim of the '213 Patent</b>	<b>Exemplary Citations to Fratti</b>
<p>[5.0] 5. The delivery system of claim 1, each of the at least one first, fastener further comprising a channel, the second fastener defining a shoulder, the shoulder adapted to be received within and secured with the channel of at least one of the first fasteners.</p>	<p>Fratti discloses this limitation:</p> <p>FIG. 5 is a side view depicting an exemplary bag-type container 500, formed in accordance with another embodiment of the invention. Bag-type container 500 preferably includes at least one additional pair of closure mechanisms disposed along a periphery of at least a portion of a second edge of the container. The access opening or mouth of bag-type container 500 is thus provided along adjacent edges (e.g., side edge 512 and top edge 516) of the container. Wall panels of bag-type container 500 (of which only one wall panel, 518, is shown for clarity) are joined together or integral along at least a portion of bottom edge 514 and side edge 510. The larger opening beneficially facilitates inserting bulky, unwieldy items into bag-type container 500.</p> <p>Specifically, bag-type container 500 includes a reversible fastener comprising at least a first closure mechanism 502 disposed along at least a portion of a top edge 516 of the container on an exterior face of each a pair of wall panels forming the container. The reversible fastener further includes a second closure mechanism 504 disposed along at least a portion of a first side edge 512 of bag-type container 500 on the exterior face of each of the wall panels, a third closure mechanism 506 disposed along at least a portion of top edge 516 on an interior face of each of the wall panels, and a fourth closure mechanism 508 disposed along at least a portion of the first side edge 512 of the container on the interior face of each of the wall panels.</p> <p>Each of the closure mechanisms 502, 504, 506, 508 preferably comprises at least first and second complementary interlockable components adapted for mutually facilitating alignment and interlocking closure engagement with one another in order to seal bag-type container 500, for example in a manner similar to that described above in connection with bag-type container 100 shown in FIG. 1. When used in a standard manner, bag-type container 500 may be sealed by engaging third and fourth closure mechanism 506 and 508, respectively, disposed on interior faces of the wall panels</p>

Asserted Claim of the '213 Patent	Exemplary Citations to Fratti
	<p>along top edge 516 and side edge 512. Likewise, bag-type container 500 is relatively easily opened from top edge 516 and side edge 512 by separating manipulation of the first and second complementary interlockable components of third and fourth closure mechanisms 506 and 508, respectively. First and second closure mechanisms 502 and 504, respectively, may be used for stacking multiple bag-type containers together, in a manner similar to that described above in connection with FIGS. 4A and 4B. When the bag-type container 500 is turned inside out, first and second closure mechanisms 502 and 504, respectively, are used to control access to the interior of the container, and third and fourth closure mechanisms 506 and 508, respectively, may be used for stacking multiple containers together.</p> <p>Fratti, 6:40-7:22.</p> <p>The access opening 113 of bag-type container 100 is adapted to be closed and opened by a reversible fastener comprising at least first and second separable and resealable closure mechanisms 114 and 120, respectively. The reversible fastener preferably runs along substantially the entire length of the top edge 112 of the container. First closure mechanism 114 is preferably provided along at least a portion of the top edge 112 of the container. First closure mechanism 114 preferably includes first and second complementary interlockable components 116 and 118, respectively, which can be coupled together or interlocked. First complementary interlockable component 116 is disposed on an interior face of wall panel 104 proximate the top edge 112. Likewise, second complementary interlockable component 118 is disposed on an interior face of opposing wall panel 102 proximate the top edge 112. First and second complementary interlockable components 116, 118 may be formed integrally with their respective wall panels, 104, 102, such as, for example, by extrusion. Alternatively, first and second complementary interlockable components 116, 118 may be affixed to their respective wall panels, 104, 102, for example by fusing, adhesive, or some other attachment means. It is to be understood, however, that the invention is not limited to the method of forming the first and second complementary interlockable components 116, 118 on wall panels 104, 102.</p> <p>Fratti, 3:40-64.</p>

Asserted Claim of the '213 Patent	Exemplary Citations to Fratti
	<p data-bbox="709 321 865 365"><i>FIG. 2</i></p>  <p data-bbox="678 1136 856 1174">Fratti, FIG. 2.</p>

Asserted Claim of the '213 Patent	Exemplary Citations to Fratti
	<p data-bbox="982 293 1115 329"><i>FIG. 5</i></p>  <p data-bbox="678 951 856 987"><u>Fratti, FIG. 5.</u></p>

Asserted Claim of the '213 Patent	Exemplary Citations to Fratti
	<p><b>FIG. 3</b></p>  <p>Fratti, FIG. 3.</p> <p>FIG. 3 is a cross-sectional view illustrating an exemplary reversible fastener 300, formed in accordance with another embodiment of the present invention. Fastener 300 may be provided along at least a portion of a top edge 318 of a resealable bag-type container including first and second wall panels, 302 and 304, respectively, as shown. Fastener 300 includes at least first and second closure mechanisms. The first closure mechanism comprises first and second complementary interlockable components, 310 and 312, respectively, which can be coupled together or interlocked. First complementary interlockable component 310 is disposed on an interior face 316 of first wall panel 302 proximate the top edge 318. Likewise, second complementary interlockable component 312 is disposed on an interior face 316 of second wall panel 304 proximate the top edge 318. First and second complementary interlockable components 310, 312 may be formed integrally with their respective wall panels 302, 304, such as, for example, by extrusion. Alternatively, first and second complementary interlockable</p>

Asserted Claim of the '213 Patent	Exemplary Citations to Fratti
	<u>components 310, 312 may be affixed to their respective wall panels 302, 304 using any known attachment methodology (e.g., heat fusion, adhesive, etc.).</u>  <u>Fratti, 5:5-27.</u>

**Exhibit 710****U.S. Pat. No. 10,105,213 in view of U.S. Pat. App. Pub. No. 2007/0038310 to Guetty (“Guetty”)**

As described in detail below, Guetty anticipates and/or renders obvious claims 1 and 5 of U.S. Patent No. 10,105,213 to Weinzwieg (the “213 Patent” or “Patent-in-Suit”), which was filed on December 29, 2015 and issued on October 23, 2018, (collectively, the “Asserted Claims”) under 35 U.S.C. § 102 and/or § 103, either alone or in combination with other prior art references, and/or in combination with the knowledge of a person of ordinary skill, as set forth in the following chart. Guetty anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit as those claims have been applied by Plaintiff NovaPlast Corporation (“NovaPlast” or “Plaintiff”) in its Infringement Contentions and as construed by the Court in its [Markman] Opinion & Order dated July 26, 2023 (Dkt. 73) (the “Markman Order”) ~~or under Defendants’ understanding of the proper construction of the claims~~. To the extent it is found Guetty or the additional references cited herein ~~does~~ not expressly disclose certain limitations in the asserted claim, such limitations are inherent.

Guetty was originally filed on Jul. 16, 2004 and published on Feb. 15, 2007, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Guetty. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Guetty (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Guetty and/or its prior art status, as evidence that the technology described in Guetty anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Zochowski was originally filed on Jun. 19, 2012 and published on Aug. 14, 2014, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Zochowski. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Zochowski (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Zochowski and/or its prior art status, as evidence that the technology described in Zochowski anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Priessman ‘208 was originally filed on Aug. 11, 2014 and published on Jan. 29, 2015, and is a continuation of application No. PCT/US12/24917 which published as WO2013122568 on Aug. 22, 2013, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Priessman ‘208. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the

technology described in Priessman '208 (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Priessman '208 and/or its prior art status, as evidence that the technology described in Priessman '208 anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Ronsonet was originally filed on Nov. 8, 1990 and issued on Jan. 7, 1992, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Ronsonet. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Ronsonet (including product samples, and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Ronsonet and/or its prior art status, as evidence that the technology described in Ronsonet renders obvious the Asserted Claims of the Patent-in-Suit.

Kruse was originally filed on Nov. 12, 2009 and issued on Apr. 8, 2014, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Kruse. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Kruse (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Kruse and/or its prior art status, as evidence that the technology described in Kruse anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

Fratti was originally filed on Jan. 31, 2007 and issued on Sept. 11, 2012, and thus is available as prior art at least under 35 U.S.C. § 102(a). The following chart includes references to the structure, function, operation, and/or features of the technology described in Fratti. Defendants reserve the right to present direct evidence of the structure, function, operation, and/or features of the technology described in Fratti (including product samples and/or witness testimony) and/or its prior art status, and to present alternative or additional documents concerning the structure, function, operation, and/or features of the technology described in Fratti and/or its prior art status, as evidence that the technology described in Fratti anticipates and/or renders obvious the Asserted Claims of the Patent-in-Suit.

The cited portions of Guetty, Zochowski, Priessman '208, Ronsonet, Kruse and Fratti are merely illustrative, and Defendants reserve the right to rely on alternative or additional evidence, including uncited portions of Guetty, Zochowski, Priessman '208, Ronsonet, Kruse or Fratti. Where the chart below states that Guetty “describes,” “discloses,” or “provides for” a limitation, such disclosure may be express, inherent, or implicit. If not anticipated, one or more claims of the Patent-in-Suit are rendered obvious in light of Guetty alone or Guetty



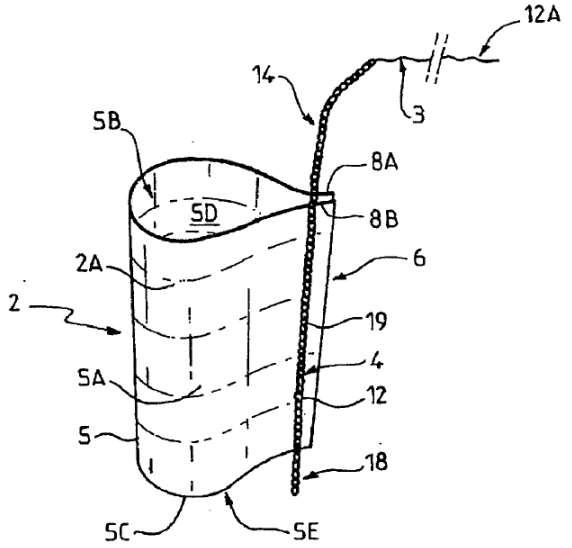
in combination with Zochowski, Priessman '208, Ronsonet, Kruse and Fratti or other prior art references and/or with the knowledge of a person of ordinary skill in the art.

This chart is subject to all reservations, objections, and disclaimers in Defendants' Amended Initial Invalidation Contentions and any amendment, supplement, or modification thereof, which are incorporated herein by reference in their entirety. Nothing stated herein shall be treated as an admission or suggestion that Defendants agree with NovaPlast regarding either the scope of the Asserted Claims or the claim constructions advanced by NovaPlast in its Infringement Contentions or anywhere else, or that any of Defendants' accused products meet any limitation of the Asserted Claims. ~~Nothing stated herein shall be construed as an admission or a waiver of any particular construction of any claim term.~~ Nothing stated herein shall be construed as an admission that the Asserted Claims are directed to patent-eligible subject matter. Defendants also reserve all rights to challenge any of the claim terms herein under 35 U.S.C. § 112, including by arguing that they are indefinite, not supported by the written description, and/or not enabled. Nothing stated herein shall be construed as an admission or waiver with respect to the effective filing date of the Asserted Claims.

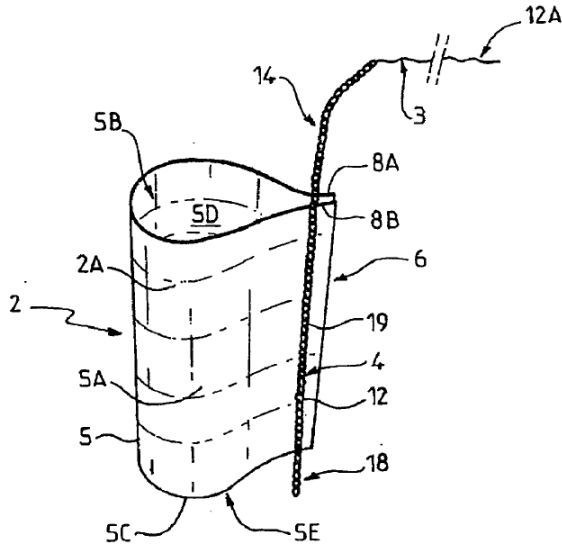
**U.S. Pat. No. 10,105,213 in view of  
U.S. Pat. App. Pub. No. 2007/0038310 to Guetty (“Guetty”)**

**CLAIM 1**

<b>Asserted Claim 1 of the ‘213 Patent</b>	<b>Exemplary Citations to Guetty</b>
<p>[1.p] 1. A delivery system adapted to facilitate insertion of a prosthetic implant through a surgical opening, the system comprising:</p>	<p>To the extent the preamble is limiting, Guetty discloses this limitation:</p> <p style="padding-left: 40px;">This invention also relates to a case for introduction of a plastic surgery implant into the body of a patient..</p> <p>Guetty, [0005].</p> <p style="padding-left: 40px;"><u>The kit in accordance with the invention is preferentially designed to make possible implantation through an incision previously made by the Surgeon.</u></p> <p style="padding-left: 40px;"><u>In the specific case of mammary implants, the kit in accordance with the invention can be adapted in particular to implantation by the axillary, Sub-mammary, peri-areolar or trans-areolar route.</u></p> <p>Guetty, [0060] – [0061].</p>
<p>[1.1] a flexible elongated member defining a proximal end and a distal end, the proximal end formed opposite the distal end and defining a closed end, the distal end defining a longitudinal opening;</p>	<p>Guetty discloses this limitation:</p> <p><u>Guetty discloses a flexible elongated member, for example, sheath 5.</u></p>

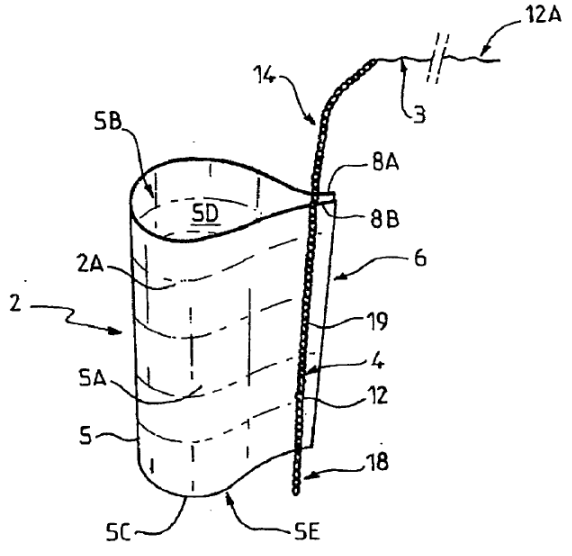
Asserted Claim 1 of the '213 Patent	Exemplary Citations to Guetty
	 <p data-bbox="903 868 997 917">FIG. 1</p> <p data-bbox="682 933 871 966">Guetty, FIG. 1.</p> <p data-bbox="682 1006 1890 1039">Guetty discloses the sheath 5 has an open distal end 5E and can have a closed proximal end 5D.</p> <p data-bbox="724 1055 1848 1307">To best advantage, case 2 comprises a sheath 5, presenting a shape that is essentially tubular. Sheath 5 is delimited by a lateral envelope 5A extending between a proximal end 5B and a distal end 5C. In the exemplary embodiment shown in FIG. 1, the sheath comprises an axial opening 5E, 5D at each of its distal and proximal ends. For all of this it is altogether conceivable, without leaving the framework of the invention, that sheath 5 could be closed at one of its ends, more preferably at its proximal end 5D, or even at its two ends.</p> <p data-bbox="724 1347 934 1380">Guetty, [0097].</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Guetty
	<p>To best advantage, sheath 5 is constructed from a material that is flexible but essentially non-elastic. In other words, the material making up sheath 5 is chosen to present an ability to be folded or rolled, while presenting a certain longitudinal and transverse rigidity, after the fashion of a sheet of paper.</p> <p>Guetty, [0112]</p> <p>It is, however, altogether conceivable, without on this account leaving the context of the invention, that case 2 might be constructed from a material presenting an elastic character, such as a biocompatible silicone polymer.</p> <p>Guetty, [0115].</p>
<p>[1.2] the distal end including a first longitudinal edge and a second longitudinal edge, the first longitudinal edge and second longitudinal edge further defining the longitudinal opening,</p>	<p>Guetty discloses this limitation:</p> <p><u>Guetty discloses a longitudinally oriented opening, referred to as lateral opening 6, extending from the distal end of Guetty's device.</u></p> <p><u>Guetty's longitudinal opening comprises two opposite edges 8A and 8B that are closed by a "locking means 4." See Guetty, [0133]-[0134].</u></p> <p>Sheath 5 is fitted with at least one lateral opening 6 arranged over all or part of its length. Said lateral opening 6 may extend, as shown in FIG. 1, essentially longitudinally over the length of sheath 5. It is altogether conceivable, without on this account leaving the framework of the invention, that this lateral opening 6 might extend in any other way, and for example transversally or helically. Said lateral opening 6 is closed by locking means 4 when case 2 is in the closed configuration (FIG. 1), said lateral opening 6 being opened up, in order to make possible the deformation of implant 1 into its functional configuration, when case 2 is in the open configuration (not shown).</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Guetty
	<p>Preferentially, sheath 5 is split over all or part of its length, said split constituting lateral opening 6.</p> <p>Guetty, [0099]-[00100].</p>  <p>FIG.1</p> <p>Guetty, FIG. 1.</p> <p><u>a case is supplied or manufactured, designed to envelope said implant in the introduction configuration, said case essentially presenting, when it is in the closed configuration, the shape of a sheath, said method being characterised in that it comprises a step for insertion of the implant into the sheath in which: the implant is shaped in the introduction configuration, then the implant is progressively constrained along its length by means of a jig, so as to reduce the cross-section of said implant,</u></p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Guetty
	<p><u>while simultaneously covering the implant with the sheath in the closed configuration.</u></p> <p>Guetty, [0037] – [0040]</p>
<p>[1.3] at least one first fastener formed on the elongated member adjacent the first longitudinal edge,</p> <p>and a second fastener formed on the elongated member adjacent the second longitudinal edge;</p> <p>[1.4] the second fastener adapted to matingly engage with the at least first fastener and to close the longitudinal opening,</p>	<p>Guetty discloses this limitation:</p> <p><u>Guetty's longitudinal opening comprises two opposite edges 8A and 8B that are closed by a "locking means 4."</u></p> <p>To best advantage, the periphery of the lateral opening 6 of sheath 5 is fitted with eyelets 13 designed to be assembled by single-thread chain stitch sewing in order to close said opening 6.</p> <p>Within the framework of the exemplary embodiment of sheath 5 involving a textile lattice 8 or a fabric, eyelets 13 are delimited by the mesh of lattice 8 (or of the fabric) located in proximity to and along the two opposite edges 8A, 8B designed to be interlocked. In this case, the chain stitches confine, two by two, the weft threads 10 of the opposite edges 8A, 8B as shown in FIG. 2. The chain stitch is thus constructed so that it locks the relative motion of edges 8A, 8B and prevents their spreading or coming apart. However, when traction is exerted on the terminal end 12A of thread 12, then the chain stitch comes undone, which has the effect of doing away with any bond of closure between edges 8A, 8B.</p> <p>Guetty, [0133]-[0134].</p> <p><u>Guetty discloses that the locking means 4 can comprise matingly engaging first and second fastener structures formed adjacent to edges 8A and 8B, respectively. Guetty's matingly engaging structures can be in the form of a Ziplock zipper system.</u></p> <p>According to an alternative exemplary embodiment of locking means 4, it is possible to conceive, instead and in place of the chain stitch seam, the implementation of a miniaturised "zipper" system, the mobile element of this "zipper" being linked to a</p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Guetty
	<p>traction thread forming the opener members.</p> <p>According to another alternative exemplary embodiment, locking means 4 can be formed from a “Ziplock®” zipper system, said zipper making possible the opening or closing of case 2, and being to this end linked to a traction thread forming opener member 3.</p> <p>According to a third alternative exemplary embodiment, locking means 4 is constructed with a “Velcro®” type closure, opener member 3 being formed from a thread arranged to exert a separation force on the complementary “Velcro®” elements, when traction is exerted on said thread.</p> <p>Guetty, [0145]-[0147].</p> <p><u>Locking means 4 is functionally linked to the opener member 3, in Such a way that when the opener member 3 is activated, it cancels the effect of locking means 4, which makes it possible for case 2 to pass into the open configuration.</u></p> <p><u>Thus, case 2 cannot pass from its closed configuration to its open configuration except when the opener member 3 is activated, and remains insensitive to any other possible external applied force.</u></p> <p><u>Case 2 in the closed configuration is thus, by its construction, naturally locked in the closure position.</u></p> <p><u>Guetty, [0094]-[0096].</u></p>

Asserted Claim 1 of the '213 Patent	Exemplary Citations to Guetty
	 <p style="text-align: center;">FIG. 1</p> <p>Guetty, FIG. 1.</p>
<p>[1.5] whereby a predetermined size distal opening is formed based on the engagement of the second fastener with the at least one first fastener, the distal opening sized to allow the prosthetic implant to be urged therethrough.</p>	<p>Guetty discloses this limitation:</p> <p><u>Guetty discloses that closing the locking mechanism 4, e.g., matingly engaging the opposing Ziplock zipper structures adjacent to edges 8A and 8B, serves to close the longitudinal opening 6 and form a distal opening 5E, which has a predetermined size.</u></p> <p><u>According to another alternative exemplary embodiment, locking means 4 can be formed from a “Ziplock®” zipper system, said zipper making possible the opening or closing of case 2, and being to this end linked to a traction thread forming opener member 3.</u></p>



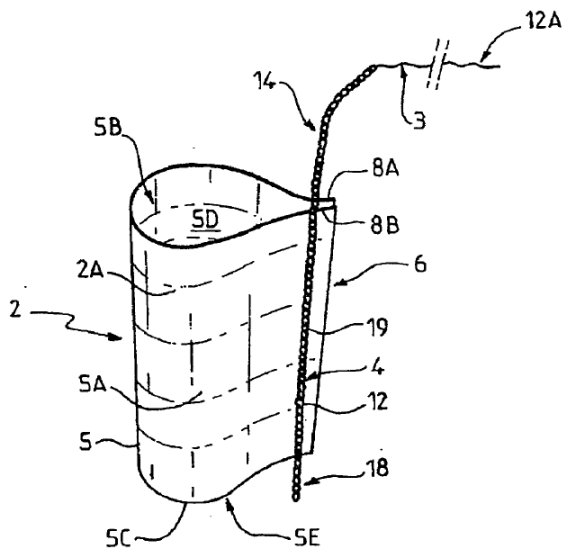
Asserted Claim 1 of the '213 Patent	Exemplary Citations to Guetty
	<p><u>Guetty, [0146].</u></p> <p>a case shaped to envelope said implant in the introduction configuration, said case being provided with an opener member that can be activated by positive action making it possible for it to pass on the one hand from a closed configuration, in which it confines implant in its introduction configuration to, on the other hand, an open configuration, in which it enables deformation of said implant into its functional configuration,</p> <p>Guetty, [0032].</p> <p>Locking means 4 is functionally linked to the opener member 3, in such a way that when the opener member 3 is activated, it cancels the effect of locking means 4, which makes it possible for case 2 to pass into the open configuration.</p> <p>Guetty, [0094].</p> <p><u>Guetty discloses that the distal opening 5E has a size that allows a prosthetic implant to be urged therethrough.</u></p> <p><u>“then, the pre-constrained implant 1 is introduced into sheath 5 through said at least one axial opening 5E,</u></p> <p><u>Guetty, [0162].</u></p> <p>Case 2 is designed to contain and sheath implant 1 in the introduction configuration so as to form with said implant a streamlined whole, compact and with a surface that is regular overall, in order to facilitate introduction into the patient's body.</p> <p>Case 2 thus constitutes a case for introduction of plastic surgery implant 1. This means that case 2 is designed and proportioned to answer to the specific technical and medical requirements linked to the subcutaneous placement of a plastic surgery implant, of the mammary implant type.</p>

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	<p>In the specific case in which the plastic surgery implant 1 is a mammary implant, case 2 is designed and proportioned to answer to the specific technical and medical requirements linked to the placement of such a mammary implant.</p> <p>More particularly, case 2 is itself designed to be partially or totally introduced under the patient's skin, in such a way as to bring implant 1 to its final subcutaneous emplacement. The characteristics of case 2 (atraumatic, sterile character, etc.) are therefore quite obviously adapted to this introduction, certainly temporary, within the patient's body.</p> <p>Guetty, [0084]-[0087].</p> <p><u>Implant 1, which was previously placed in the introduction configuration, is next forcibly introduced into entry opening 23A by its distal end 1A, over a length X sufficient to establish frictional contact between said proximal end 1A and the corresponding Zone 27 of sheath 5.</u></p> <p><u>Once this step for priming of implant 1 is carried out, all it then takes is to exert traction on distal end 5C of sheath 5 coaxially in tube 23 to pull implant 1 by friction towards the opening of tube 23 opposite the entry opening 23A</u></p> <p><u>This displacement of implant 1 is therefore carried out without exerting direct effort on said implant 1A, but simply by using the frictional dragging of implant 1 along the inner surface of sheath 5.</u></p> <p><u>The progression of implant 1 in hollow tube 23 thus makes it possible to unroll, on said implant, the proximal part 24 of sheath 5 which was folded back on the outer surface of hollow tube 23.</u></p> <p><u>Thus, radial compression and covering up of implant 1 are simultaneously achieved, without exerting direct traction effort on the latter, which makes it possible to minimise</u></p>

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	<p data-bbox="730 272 1239 305"><u>any risk of deterioration of the implant.</u></p> <p data-bbox="678 324 991 357">Guetty, [0172] – [0176].</p> <div data-bbox="701 399 1533 711"> </div> <p data-bbox="1073 768 1182 816">FIG. 6</p> <p data-bbox="678 898 873 930"><u>Guetty, FIG. 6.</u></p> <p data-bbox="678 995 1894 1287">To the extent NovaPlast alleges that this limitation is not expressly or inherently disclosed in Guetty, it would have been obvious in light of the knowledge of a person of ordinary skill in the art. A person of ordinary skill in the art would have been motivated to combine Guetty with any of the other references identified in <del>Defendants' Amended Initial Invalidation Contentions regarding the '213 Patent below</del> at least to the extent they desired to provide a device with a longitudinal opening that is closed by a first and second fastener, whereby engagement of the first and second fasteners –forms a predetermined size distal opening that is sized to allow a prosthetic implant to be urged therethrough.</p> <p data-bbox="678 1328 1879 1393">For example, at least the references listed below disclose a device with a longitudinal opening that is closed by a first and second fastener, whereby engagement of the first and second</p>

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	<p>fasteners forms a predetermined size distal opening that is sized to allow a prosthetic implant to be urged therethrough.</p> <p><del>U.S. Pat. No. 5,121,779 to Green (“Green”), Exhibit 1 at 1.5.</del></p> <p>U.S. Pat. No. 9,168,126 to Preissman (“Preissman ‘126”), Exhibit <u>12</u> at 1.5.</p> <p>U.S. Pat. App. Pub. No. 2014/0228951 to Zochowski (“Zochowski”), Exhibit <u>23</u> at 1.5.</p> <p>U.S. Pat. App. Pub. No. 2015/0032208 to Priessman (“Priessman ‘208”), Exhibit <u>43</u> at 1.5.</p> <p>U.S. Pat. No. 5,078,189 to Ronsonet (“Ronsonet”), Exhibit <u>54</u> at 1.5.</p> <p><del>U.S. Pat. No. 4,651,504 to Bentsen (“Bentsen”), Exhibit 6 at 1.5.</del></p> <p><del>U.S. Pat. No. 4,825,915 to Hess (“Hess”), Exhibit 7 at 1.5.</del></p> <p>U.S. Pat. No. 8,690,428 to Kruse (“Kruse”), Exhibit <u>85</u> at 1.5.</p> <p>U.S. Pat. No. 8,262,289 to Fratti (“Fratti”), Exhibit <u>69</u> at 1.5.</p> <p>The intended use of the device of claim 1, the type of object for insertion, and the size of the object are not material limitations.</p>

**CLAIM 5**

<b>Asserted Claim of the '213 Patent</b>	<b>Exemplary Citations to Guetty <u>in view of Ronsonet</u></b>
<p>[5.0] 5. The delivery system of claim 1, each of the at least one first, fastener further comprising a channel, the second fastener defining a shoulder, the shoulder adapted to be received within and secured with the channel of at least one of the first fasteners.</p>	<p>Guetty discloses <del>this limitation:</del> <u>the system of claim 1, from which this claim 5 depends, for the reasons stated above.</u></p> <p><u>Guetty discloses a plurality of first fasteners and a second fastener.</u></p> <p>—</p>  <p>FIG.1</p> <p>Guetty, FIG. 1.</p> <p>[0133] <u>To best advantage, the periphery of the lateral opening 6 of sheath 5 is fitted with eyelets 13 designed to be assembled by single-thread chain stitch sewing in order to close said opening 6.</u></p>

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	<p><u>Within the framework of the exemplary embodiment of sheath 5 involving a textile lattice 8 or a fabric, eyelets 13 are delimited by the mesh of lattice 8 (or of the fabric) located in proximity to and along the two opposite edges 8A, 8B designed to be interlocked. In this case, the chain stitches confine, two by two, the weft threads 10 of the opposite edges 8A, 8B as shown in FIG. 2. The chain stitch is thus constructed so that it locks the relative motion of edges 8A, 8B and prevents their spreading or coming apart. However, when traction is exerted on the terminal end 12A of thread 12, then the chain stitch comes undone, which has the effect of doing away with any bond of closure between edges 8A, 8B.</u></p> <p><u>Guetty, [0133] –[0134].</u></p> <p><u>Guetty further discloses the locking mechanism can include first fasteners comprising channels and second fasteners comprising shoulders.</u></p> <p>According to an alternative exemplary embodiment of locking means 4, it is possible to conceive, instead and in place of the chain stitch seam, the implementation of a miniaturised “zipper” system, the mobile element of this “zipper” being linked to a traction thread forming the opener members.</p> <p>According to another alternative exemplary embodiment, locking means 4 can be formed from a “Ziplock®” zipper system, said zipper making possible the opening or closing of case 2, and being to this end linked to a traction thread forming opener member 3.</p> <p>According to a third alternative exemplary embodiment, locking means 4 is constructed with a “Velcro®” type closure, opener member 3 being formed from a thread arranged to exert a separation force on the complementary “Velcro®” elements, when traction is exerted on said thread.</p> <p><u>Guetty, [0145]-[0147].</u></p>

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	<p>To the extent NovaPlast alleges that this limitation is not expressly or inherently disclosed in Guetty, it would have been obvious in light of the knowledge of a person of ordinary skill in the art. A person of ordinary skill in the art would have been motivated to combine Guetty with <del>any of the other the</del> references identified in Defendants' Initial Invalidity Contentions regarding the <del>'213 Patent</del> below at least to the extent they desired using a <u>plurality of first fasteners</u> comprising a channel and a <u>second</u> fastener comprising a shoulder that is received and secured within <del>the a</del> channel.</p> <p>For example, at least the references listed below disclose a device with an opening that is closed by a <u>plurality of first fasteners</u> comprising a channel and a second fastener comprising a shoulder, the shoulder adapted to be received within and secured with the channel of the first fasteners.</p> <p><del>U.S. Pat. No. 5,121,779 to Green ("Green"), Exhibit 1 at 5.0.</del>  U.S. Pat. App. Pub. No. 2014/0228951 to Zochowski ("Zochowski"), Exhibit 3 at 5.0.  U.S. Pat. No. 5,078,189 to Ronsonet ("Ronsonet"), Exhibit 5 at 5.0.  <del>U.S. Pat. No. 4,651,504 to Bentsen ("Bentsen"), Exhibit 6 at 5.0.</del>  U.S. Pat. No. 8,690,428 to Kruse ("Kruse"), Exhibit 8 at 5.0.  U.S. Pat. No. 8,262,289 to Fratti ("Fratti"), Exhibit 9 at 5.0.</p> <p><u>More specifically, Ronsonet discloses the limitations of claim 5:</u></p> <p><u>What is provided is an apparatus which includes a rectangular sheet of flexible plastic, the first face of the sheet which includes a plurality of parallel spaced apart channels, and on the second face of the sheet including a pair of raised members, one raised member positioned substantially along a first edge of the sheet, and the second raised member positioned substantially perpendicular thereto along the bottom edge of the sheet, so that when the sheet is configured into a funnel shape, one of the raised locking members is mated into the channel members, to form a sealed juncture thereon, and for</u></p>

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	<p><u>defining a sealed cone having an enlarged upper end and a reduced lower spout end, defining an overall funnel member.</u></p> <p><u>Ronsonet, 1:64-2:9</u></p> <p><u>With that locking concept in mind, reference is made now to FIGS. 3 and 4 of the apparatus, which illustrates the manner in which the apparatus is configured into a shape to function as an adjustable funnel apparatus 50 as illustrated in FIG. 4. It is quite commonplace that if one takes a substantially rectangular sheet as illustrated in FIGS. 1 and 2, that if one were to configure the positioning of the sheet as illustrated in FIG. 3, by rotating one face of the sheet in a circular fashion, that the sheet could be configured into a funnel apparatus as illustrated in FIG. 4. With that general concept in mind which is quite commonly known, reference is made to FIG. 3 where it is seen that the edge 18 of the apparatus has been formed into a circular pattern in the direction of arrow 40, and face 22 having the plurality of channel members 28 is being circulated around so that one of the parallel channel members 28 is brought into parallel locking alignment with horizontal raised locking member 38, and horizontal channel member 34 is brought into parallel locking alignment with vertical raised locking member 36 along edge 20, as illustrated in phantom view in FIG. 4. Therefore, once the locking members have been pressed into locking relationship as with a ZIPLOCK® locking arrangement, FIG. 4 would define the funnel member 50 having an upper enlarged spout area 52, a continuous annular wall portion 54 which is then sealed along a common edge 56 via locking members 28, 38 and sealed along a top edge 58 via the locking relationship of locking members 34, 36. Further, as illustrated there would be further defined a reduced downspout opening 60 which is formed as a result of the manner in which the rectangular sheet 12 is placed into the configuration as illustrated.</u></p> <p><u>Turning now to the plurality of channel members 28 as they would configure into locking relationship with raised members 34, 36, as was discussed earlier, each of the channel members 28 are positioned in parallel relationship for defining a specific dimensional distance therebetween. Therefore, this dimensional distance as defined by the letter A in FIG. 3, results in a particular configuration of the diameter of downspout</u></p>

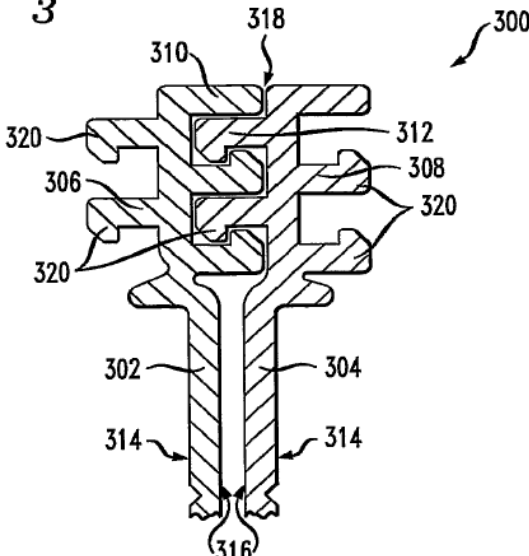


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	<p>60. There fore, as raised locking edge 38 is configured into locking engagement with a particular channel 28, the diameter of the downspout 60 formed thereby is of a <u>dimension in direct relation to the change in the distance between the parallel channels 28</u>. For example, if one were to assume that the diameter of downspout 60 in FIG. 4 is inch in the position that locking channel 28 locks with raised locking member 38, then <u>were locking member 38 moved to the next channel 28B, as illustrated in FIG. 4, if that distance would be for example of an inch, then the diameter of the downspout 60 would be reduced of an inch</u>. Therefore, with this relationship in mind, it is foreseen that the <u>plurality of channels 28 allow one therefore to matingly engage a particular channel 28 with locking member 38, depending on the diameter of downspout 60 that one wishes to achieve in the final configuration of funnel member 50.</u></p> <p><u>Ronsonet, 3:51-4:41.</u></p> <div data-bbox="682 844 1722 1315"> <p>FIG. 3</p> <p>FIG. 4</p> </div> <p><u>Ronsonet, FIG. 3 – 4.</u></p>

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	<p><u>It should be fully understood that this particular embodiment should not be limiting in the sense that the plurality of channel member 28 do not necessarily have to be evenly spaced apart, but could be configured into a particular dimensional arrangement i.e. one inch apart or even having a plurality of channel members along face 22 which would allow one to configure the funnel in a single funnel size, or in two or three or more funnel sizes depending on the location of the channel members 28. Therefore, it is foreseen that the sheets could be formed in many configurational sizes, and not limited to the sizes as illustrated in the Figures.</u></p> <p><u>Ronsonet, 4:42-53.</u></p> <p><u>1. An adjustable funnel apparatus comprising:</u></p> <p><u>a) a substantially flexible sheet member, having a first face and a second face;</u></p> <p><u>b) at least one first channel running substantially along the width of said first face;</u></p> <p><u>c) a second channel running along a portion of the length of the first face and substantially perpendicular to the positioning of the at least one first channel;</u></p> <p><u>d) a first raised locking member running along adjacent an edge of the second face of the sheet member;</u></p> <p><u>e) a second raised locking member running along the lower edge of the second face and substantially perpendicular to the alignment of the first locking member;</u></p> <p><u>f) means for positioning the sheet member into a configuration so that one of the at least one first channel lockingly mates with the second raised locking member and the second channel mates with the first locking member, for defining a funnel shaped apparatus sealed by the locking engagement of one of the at least one first channel and</u></p>

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	<p><u>the second channel to the second and first locking members respectively.</u></p> <p><u>Ronsonet, claim 1, 4:62-5:18.</u></p> <p><u>One skilled in the art would be motivated to modify Guetty according to Ronsonet to utilize a plurality of first fasteners on one longitudinal edge of the elongated sleeve and a complementary second fastener on the opposing longitudinal edge of the elongate sleeve which one selected first fastener and second fastener can be matingly engaged for forming a locked seal along the longitudinal edge and thereby define the size of the distal opening.</u></p> <p><u>Guetty recognizes the problem of having to construct a sleeve configured to expel pre-filled, solid, and/or semi-solid implants through an opening at a distal end of the sleeve into a tissue pocket, wherein at least the silicone implants vary in size and the dimension of the sleeve may vary. Guetty, [0189], [0025], [0064], [0085]-[0086].</u></p> <p><u>Ronsonet recognizes this same problem for funnels (i.e., a truncated, generally conical sleeve made of a flexible plastic material) that have to be provided with different sized distal end openings according to the specific environment in which it will be used, and proposes an alternative solution that allows the user to select the size of the distal opening 60 through the implementation of a plurality of spaced apart raised members 36, 38 along one longitudinal edge of the sleeve, and a complementary fastener of channel members 28, 34 on the opposing longitudinal edge of the sleeve, wherein the selection of different ones of the raised members to mate with the opposing channel members along their entire length to form a “ziplocked” seal closing that longitudinal edge will result in different sized distal openings 60 according to the distances between the different ones of the plurality of raised channels 36, 38. (Ronsonet Col. 3, line 34 - Col. 4, line 41). Ronsonet also discloses that this solution has the advantage of providing a single product that can be sized by the user to have the desired sized distal opening for the environment of use and reduced size for storage when not in use. (Ronsonet Col. 1, lines 25-44).</u></p> <p><u>One skilled in the art would be motivated to make the substitution because an adjustable funnel having a longitudinal seal formed by the locking raised members and opposing channels would</u></p>

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	<p><u>allow for improved scale and efficiency in manufacturing and reduced inventory in having a device with adjustable dimensions rather than stocking multiple different sized devices, and improved efficiency in use by allowing the user to select the size, and if the initial size was incorrect then the “ziplocked” seam could be unlocked and a different raised member selected and the seam relocked at the correct size, whereas in the Guetty disclosure the sleeve having an incorrect distal opening size would have to be discarded and a new sleeve used, and there is a reasonable expectation that the substitution would be successful and would result in a sleeve having adjustable dimensions to established the proper sized distal opening for the implant to be delivered therethrough into the tissue pocket. One skilled in the art would understand that this substitution could be implemented successfully without impacting the need for preserving the sterile environment of the Guetty device.</u></p> <p><u>Therefore, combining the teachings of Guetty and Ronsonet is a combination of familiar elements according to known methods that does no more than yield a predicable result, and such a combination is obvious.</u></p> <p><u>By way of further example, Fratti discloses first fasteners comprising a plurality of channels on one side of a bag opening and one or more protrusions on the opposing side of the bag opening that are configured to matingly engage to close the opening. See e.g., Fratti, Exhibit 6, 5.0.</u></p>

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	<p data-bbox="703 284 850 316"><b>FIG. 3</b></p>  <p data-bbox="682 868 850 901"><u>Fratti, FIG. 3.</u></p> <p data-bbox="682 941 1890 1161"><u>Similarly, both Guetty and Zochowski disclose a closure mechanism for a second opening of an implant delivery device that can comprise a ziploc type of closure. See e.g., Guetty, Exhibit 7 at 5.0; Zochowski, [0080]. As would be known by a person of ordinary skill in the art, ziploc type closures can comprise one or more channels provided on one side of a bag opening and one or more complementary shaped structures (e.g., protrusions) provided on an opposing side of the opening that can be matingly engaged.</u></p>